



Technology Department

Scrambler Therapy: Implications for Chronic Pain Relief in Pediatrics

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Pain is a physical sensation experienced through a perceived or actual tissue injury (Majithia et al., 2016). When symptoms of pain persist outside the time of tissue injury and healing, it can be maladaptive and considered a chronic disease state (Majithia et al., 2016). Conventional treatments of chronic pain consist of opioids, neuroleptics, physical therapy, regional anesthesia, and neuromodulation (Campagnone & Tagliaferri, 2015). Both adults and children experience chronic pain. Characteristics of chronic pain are symptoms that endure or reoccur for at least three months (Park, Kim, Kim, & Yoo, 2017). Common conditions causing chronic pediatric pain (CPP) include cancer related neuropathic pain associated with platinum-based chemotherapeutic drugs (e.g. Cisplatin) (Park et al., 2017) and complex regional pain (CRP) a type of chronic neuropathic pain that is characteristically contained to one limb and develops due to a noxious stimulus from trauma, surgery, or a stroke (Raucci et al., 2016).

Children who experience chronic pain develop alterations in performing daily activities, which in turn may have an undesirable impact on the child's physical, psychological and social well-being (Park et al., 2017). The goal of treatment is to reduce pain to improve the child's quality of life (Majithia et al., 2016). Given the increase in prescription opioid misuse there is a need to develop alternative approaches for treating chronic pain (Lesenskyi, Maxwell, & Cruciani, 2017).

Scrambler Therapy (ST) is a noninvasive, electrocutaneous stimulation (neuromodulation) device that may prove to be a safe alternative for chronic refractory pain treatment in children. The majority of ST research demonstrates relief of symptoms in neuropathic and mixed pain syndromes in adults without serious side effects. The Food and Drug Administrations (2009) approved the Scrambler Therapy MC-5A TENS Device for: "1) Symptomatic relief of chronic, intractable pain, post-surgical, and post-traumatic acute pain, 2) Symptomatic relief of acute pain, and 3) Symptomatic relief of post-operative pain" (pp. 5-1, 5-2). Clinical trials show promising results of ST for treating chronic pain in adults (Congedi et al., 2016). This column will review ST, current clinical trials, application to pediatric chronic pain, disadvantages, and contradictions to the treatment.

Fundamental characteristics of pediatric chronic pain

To understand the indications for ST, it is essential to review the characteristics of chronic pain in children. Pediatric chronic pain disorders frequently respond inadequately to traditional pain treatments, because the pain conduit and source produces a complicated apparatus of pain mechanism (Raucci et al., 2016). Chronic pain is thought to occur due to dysregulation of the pain pathway (Raucci et al., 2016). It is postulated that in chronic pain neurons proximate to damaged tissue can trigger impulses that communicate pain data with the absence of external input (Majithia et al., 2016). The result can be somatic and sensory symptoms produced by chronic pain syndromes (i.e. peripheral neuropathy and CPS) such as sharp pain, numbness, tingling, pressure, vasomotor changes, autonomic, motor dysfunction, and central nervous system changes (Raucci et al., 2016). Moreover, patients with recurring pain stimuli can experience modifications that subsequently result in a reduced pain threshold (Majithia et al., 2016). Hence, there is damage to the nerve endings that result in pain signals that cannot turn off even though the surrounding tissue has healed.

Nevertheless, it is common practice for practitioners to prescribe pharmacological and non-pharmacological treatments to control pain. Using multimodal therapies to attain reasonable pain control can increase the side effects that patients experience (Majithia et al., 2016). Despite better understanding of chronic pain pathophysiology and different therapies, more than two-thirds of patients report inadequate pain relief (Russo, Zoratto, Tirrocchi, & Guarda, 2018). Reports in the literature show encouraging outcomes utilizing ST with various types of pain (somatic and neuropathic) syndromes (Pachman et al., 2015).

Scrambler therapy - How it works?

ST was developed by Giuseppe Marineo (2003) and a team of researchers in Rome, Italy. ST is a noninvasive, electrocutaneous stimulation (neuromodulation) device that was found to be effective in reducing pain symptoms in patients with terminal cancer who did not respond well to standard pain treatment (Majithia et al., 2016). The mechanics of ST are not well-defined, but Marineo, Iorno, Gandini, Moschini, and Smith (2012) hypothesized that the device interrupts afferent pain impulses through C-fiber surface receptors and replaces them with synthetic *no pain* data through cutaneous nerves with the application of surface electrodes surrounding the identified painful areas of the body (Park et al., 2017) (Fig. 1). Unlike the current conventional

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Fig. 1. Scrambler Therapy Model and Electrodes Application. “A typical setup to treat “stocking and glove neuropathy.” Reprinted from “Scrambler therapy for treating neuropathic pain”, by Smith and Loprinzi (2016). Scrambler therapy for treating neuropathic pain. The Foundation for Peripheral Neuropathy. Retrieved November 28, 2018 from: <https://www.foundationforpn.org/2016/12/09/scrambler-therapy-for-treating-neuropathic-pain/>.

electro-analgesia (e.g. transcutaneous electrical nerve stimulation [TENS], and implanted spinal cord devices), that block pain information, ST works through a process termed *plasticity* (Southall, 2016). The process of plasticity retrains the brain and introduces a pleasurable perception that acts as a disruption by sending a new message to nerve fibers that where accustomed to receiving noxious stimuli (Lesenskyi et al., 2017).

ST starts with the patient identifying the region of pain. A set of electrodes are placed on the area around the pain site, specifically the dermatome “A localized area of skin that has its sensation via a single nerve from a single nerve root of the spinal cord” (MedicineNet, 2016, para, 1) and not at the actual site of the pain (Park et al., 2017). The dermatomal location is used to foster the *no pain* site to cloud the systematic nervous circuit by utilizing the peripheral nerves rather than accessing the spinal cord (Majithia et al., 2016, p. 4). After the electrodes are placed, electrical stimuli are started with augmented increases in intensity until the patient encounters a sensation described as a pleasant, humming or a vibration (Majithia et al., 2016). Subsequently, the patient feels the positive sensation at the points of the electrode, as well as all dermatomes signifying the spreading of signals along the conduction pathway of the nervous system (Congedi et al., 2016) (Fig. 1).

The duration of the ST is about 30–45 min (Congedi et al., 2016). Following the completion of each session, patients often report a *soothing sensation* with pain significantly reduced or completely gone; however, the benefits of an initial ST is often short-lived (Majithia et al., 2016). On the average patients, require approximately, ten consecutive daily treatments to provide therapeutic effects that can last weeks to months. Other patients may experience a relapse in pain and require further ST (Southall, 2016).

Special considerations with Scrambler therapy

Minor complications noted with ST include skin irritation or bruising beneath the site where the electrode leads are placed (Southall, 2016). If the patient uses anticonvulsants (e.g. neurontin) for analgesic purposes, it is important to consider weaning the drug because the effects of ST is deficient especially at high doses of the drug (Marineo et al., 2012). Anticonvulsants may cause an opposing mechanism by counteracting the

stimulus to progress along the nerve fibers (Raucci et al., 2016). Concerns of ST are the cost of purchasing the equipment and training of practitioners. ST requires specialized training, and the success of treatment is known to be dependent upon correct placement of the electrodes (Congedi et al., 2016) and the regulation of the stimulation intensity (Southall, 2016).

Some insurance companies recognize the economic value of ST in comparison to expensive alternative invasive treatments (i.e. invasive regional anesthesia) (Southall, 2016), still others will not cover the treatment. The cost of ST can range anywhere from two to five hundred dollars per session, with an average of ten-sessions to provide therapeutic effects (Southall, 2016). Nonetheless, the duration of treatment has shown superior results in comparison to other common pain management therapies such as peripheral nerve block, which has a short duration of action of a local anesthetics and potential risks of an invasive procedure (Congedi et al., 2016). Therefore, ST can be a noteworthy substitute for traditional chronic pain management for a patient who requires a longer analgesic duration.

Summary of clinical trials

Like any new therapy, the significance of the practice relies upon research conducted within the adult patient population. Some of the clinical studies include chronic pain conditions such as brachial plexus injury, a wide range of refractory chemotherapy neuropathic pain induced bone and visceral metastases, failed back syndrome and spinal cord stenosis (Congedi et al., 2016). The results of the adult studies showed a decrease in pain intensity and a suspension of pain medication after one to five treatments (Marineo et al., 2012). Also, various results in pain reduction have been documented from thirty to hundred percent from baseline with a continued duration from two-weeks to three months (Coyne, Wan, Dodson, Swainey, & Smith, 2013; Moon et al., 2015; Notaro et al., 2015; Starkweather, Coyne, Lyon, Elswick, & Sturgill, 2015,). Most of the success of ST occurred with neuropathic pain syndromes (Moon et al., 2015). Treatment failure transpired with traumatic/surgical etiologies and the use of antidepressant (Moon et al., 2015). Also, it is important to note that there were no significant

complications noted or recorded with any of the studies conducted (Majithia et al., 2016).

Scrambler therapy to treat chronic pain in children

There are two case reports in the literature about the use of ST in the pediatric population. One a seven-year-old female with minimal change congenital myopathy, scoliosis with a subsequent contracture, and edema of the paravertebral musculature (Congedi et al., 2016). The child developed severe acute nociceptive and neuropathic scapular pain refractory to high dose opioids, benzodiazepams, and anti-inflammatory agents (Congedi et al., 2016). The other case is an eleven-year-old female with neuropathic pain in the mid-thigh and groin area (obturator nerve involvement) related to chemotherapy treatment (Park et al., 2017). Both cases reported similar results congruent with adult studies: ST resulted in a reduction in pain scores, decrease use in pain medication and an increased duration of pain relief over a two-month period (Congedi et al., 2016; Park et al., 2017). The overall positive outcomes and extent of pain relief with ST are thought to occur due to a remodulation in the peripheral and “central nervous systems within the calcium channels of the synapse, which are the critical focus for treating neuropathic pain” (Congedi et al., 2016, p. 5).

Conversely, opinions against ST undoubtedly endure, with opponents ascribing the value to a placebo influence (Majithia et al., 2016). The original developers of the device, Marineo et al. (2012), stated that their participation in the initial “clinical trials could perceive as a potential conflict of interest”. Yet, other researchers applied ST with various chronic pain disorders and found similar results. Lastly, critics acclaim there are no sizable, double-blinded clinical trials to appraise the efficacy of ST (Congedi et al., 2016).

Conclusion

ST is a noninvasive medical device with encouraging results and may be a safe alternative to chronic refractory pain in the pediatric patient population. The majority of the research of ST in adult patients demonstrates relief of symptoms in neuropathic and mixed pain syndromes without serious side effects. Highlighting a few of the pediatric cases published in the literature describes how ST might be beneficial to children as well. Still, more research is needed including sizable, double-blinded clinical trials to appraise the efficacy of ST for adults and children. Furthermore, deficiencies with standard therapies along with the increase of prescription opioid misuse encourages the necessity to foster alternative methodologies for treating chronic pain for both adults and children (Lesenskyi et al., 2017).

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