A novel treatment for chronic opioid use after surgery

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Case report

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abstract

In a recent article from the Center for Disease Control, the authors addressed the current opioid epidemic in America and emphasized the importance of utilizing non-opioid analgesic alternatives to opioid medication for treating chronic pain. In cases where non-opioid analgesic drugs alone have failed to produce adequate pain relief, these authors suggested that non-pharmacologic therapies should also be considered. This Case Series describes a pilot study designed to evaluate a novel non-pharmacologic approach to treating long-standing (N1 year) opioid dependency. The therapy involved the use of a high intensity cold laser device to treat three patients who had become addicted to prescription opioid-containing analgesic medication for treating chronic (residual) pain after a major operation. After receiving a series of 8–12 treatment sessions lasting 20–40 min to the painful surgical area over a 3–4 week period of time with the high intensity (42 W) Phoenix Thera-lase laser device, an FDA-approved Class IV cold laser, these patients were able to discontinue their use of all oral opioid-containing analgesic medications and resume their normal activities of daily living. At a follow-up evaluation 1– 2 months after their last laser treatment, these patients reported that they have been able to control their pain with over-the-counter non-opioid analgesics and they have remained largely opioid-free. Further larger-scale studies are needed to verify these preliminary findings with this powerful cold laser in treating opioid-dependent patients.

1. Introduction

In a recently published study by Goesling and colleagues [1], it was reported that for many patients taking opioids before joint replacement surgery, as well as some opioid-naïve patients undergoing arthroplasty procedures, chronic use of opioid analgesics continued after surgery despite the absence of joint pain. Although opioid-related side effects in the perioperative period are well-known (including nausea, vomiting, constipation, ileus, bladder dysfunction, pruritus, sedation, visual hallucinations, and ventilatory depression), there are growing concerns regarding long-term physical dependence and addiction liability with persistent opioid use after surgical procedures [2,3]. These authors also reported that prolonged use of opioids was associated with increased risks of more serious complications, including opioid use disorder, overdose, and death. Interestingly, no study of prolonged opioid use has ever demonstrated long-term (≥1 year) benefits for the users. An epidemiological study by Erikssen et al. [4] involving chronic pain patients treated with opioids for 5 yrs. provided compelling evidence that opioids were not a panacea for chronic pain. In fact, the patients' quality of life failed to improve despite escalating doses of opioids over the 5 yr study period. These authors concluded that "it is remarkable that opioid treatment of long-term/chronic non-cancer pain does not seem to fulfill any of the key outcome treatment goals, namely, pain relief, improved quality of life and improved functional capacity."

In a recent article from the Center for Disease Control (CDC), Dowell et al., conducted a review of the benefits and harms, as well as the costs, of using opioid analgesics for the treatment of chronic pain [2]. In light of the growing opioid epidemic in his country, these authors emphasized the importance of increasing the use of non-opioid analgesic drugs, as well as non-pharmacologic analgesic techniques for the management of chronic (persistent) post-surgical pain. Although non-pharmacologic analgesic techniques (e.g., acupuncture, electro-stimulation) have been successfully used for the treatment of acute and chronic pain, [5] these 'alternative' therapies have failed to achieve widespread acceptance in the medical community because of issues related to both weak marketing efforts and low reimbursement by the third party payors. Cold laser therapy is a non-invasive, non-pharmacologic modality which can be used to treat a wide variety of acute and chronic pain syndromes [6,7]. However, the vast majority of the studies reported in the medical literature have involved the use of low level (Class III) cold lasers. Although low level laser therapy (LLLT) has been reported to be effective in the treatment of superficial medication conditions (e.g., plantar fasciitis and superficial surgical procedures), [8–10] there are no LLLT study to date that have demonstrated the ability to produce clinically-significant opioid-sparing effects in opioid-dependent patients.

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We describe the treatment of three patients who had been taking opioid-containing oral analgesics for N1 year for pain control after undergoing a major surgical procedure. These patients received a series of treatments with a high intensity, non-invasive Class IV cold laser (Phoenix Thera-Lase [Dallas, Texas]). The Phoenix Thera-lase is a powerful 42 Watt high-intensity cold laser compared to Class III LLLT devices like the Erchonia (McKinney, Texas) which operate at b0.5 W). The Phoenix Thera-lase also operates at a longer infrared wavelength (namely, 1275 nm [vs. 635–660 nm]) to reduce the light absorption by melanin and hemoglobin and allow deeper penetration into the soft tissue. Laakso and colleagues [11] have discussed the importance of factors such as power (Wattage) and wavelength (nM) of the laser beam which affect the depth of penetration and light absorption. Other important factors which can influence the therapeutic effect of laser therapy include the laser pulse frequency, type of probe (single vs. multiple diodes), as well as duration and frequency of treatments [11].

We postulated that a series of 8–12 treatments with the high-intensity Phoenix thera-lase would reduce persistent pain and chronic opioid use in patients who had become opioid-dependent after undergoing a major surgical procedure. In addition, we evaluated the effect of the laser treatments on their ability to resume normal activities of daily living.

2. Case reports

The three consenting patients described below became dependent upon opioid-containing medication after undergoing a major surgical procedure and recently underwent a series of 8–12 cold laser treatments with the Phoenix Thera-lase System (Dallas, Texas).

2.1. Case 1

A 32 year old woman was involved in a motor vehicle accident 16 months ago in which she sustained serious orthopedic injuries requiring multiple surgical procedures (including placement of a titanium rod in her left femur). Although she was discharged from the hospital after 10 days on oral morphine and hydromorphone, she was later switched to an oral combination of hydrocodone/acetaminophen due to severe opioid-related side effects when she began the rehabilitation process (e.g., physical therapy). She initially presented for laser treatments in early December 2016 and was taking Narco (hydrocodone bitartrate 10 mg and acetaminophen 325 mg) 1 tablet po QID along with ibuprofen 600 mg po TID. Her baseline pain score was 4–5 at rest and 7– 8 with physical activity (using an 11-point verbal analog scale [VAS] with 0 = no pain and 10 = worst pain imaginable). The patient received a series of eight (8) treatment sessions lasting 30-40 min over a four week period with the Phoenix thera-lase, an FDA-approved class IV, noninvasive, 42 W, continuous diode cold laser manufactured by Phoenix Thera-Lase, Dallas, Texas (Model Sultra-3000). The designated painful body areas (namely, her low back, left hip and knee) were treated with a series of 60 s treatments located approximately 3–5″ apart while holding the laser hand piece 12–16″ from the skin surface to avoid overheating the treatment area. At the end of the four week treatment period, her pain at rest was reduced to 2 and only increased to 3 with physical activity. More importantly, she was able to eliminate the regular usage of the opioid-containing analgesic medication as she resumed her normal activities of daily living (e.g., hiking, water aerobics). She has remained opioid-free for 2 months after completing the initial series of laser treatments. She is currently taking oral ibuprofen 600 mg BID, PRN for pain associated with physical activity. She volunteered that has taken one Narco tablet ~1 month after the last laser treatment due to pain after a busy day moving boxes and furniture into her new apartment. She has subsequently returned for three additional laser treatments in the last two months and remains largely
'opioid-free.

2.2. Case 2

A 64 year old man sustained injuries to his lower back in a work-related accident ~20 years ago. After his spine surgery, he was discharged from the hospital with a prescription for hydrocodone/acetaminophen tablets to treat his post-surgical low back pain. Approximately 1 year ago, he was switched to Tramadol and was initially taking 8–10 tablets per day. Due to persistent pain despite the use of Tramadol, he inquired about the possibility of receiving laser therapy with the Phoenix theralase system in September 2016. When he started the laser treatments his baseline VAS pain score was 5 at rest and 7 with physical activity despite using 5–6 Tramadol pills per day. The patient received a series of 12 thera-lase treatments sessions lasting 30–40 min over a six week period to his mid- and low back region, as well as his left hip. At the end of the 6 week treatment period, his pain at rest was reduced to a 1 and only increased to a 2 with vigorous activity. The patient was able to decrease his Tramadol consumption to 1 tablet a day while working over the Christmas holidays. Over the last 1 month he has been 'opioid-free' while continuing to increase his physical activity. After completing the series of 12 thera-lase treatments, he was able to once again participate in daily physical activities with his grandchildren.

2.3. Case 3

A 44 year old woman was experiencing chronic pain in her lumbar spine and hips after undergoing back surgery ~10 years ago ("failed back syndrome"). Due to the presence of persistent 'severe' pain despite the use of 2–3 Percocet (oxycodone 5 mg/acetaminophen 325 mg) tablets per day, she inquired regarding the possibility of receiving treatments with the Phoenix thera-lase device in November 2016. Her baseline VAS pain score was 7 at rest and a 10 with physical activity. The patient received a series of 9 thera-lase treatment sessions to her low back and hip region lasting 30–40 min over a 3 week period. At the end of the 3 week period, her pain was reduced to 0 at rest and a 3 when performing her normal activities of daily living (e.g., working in her garden) despite no longer taking any opioid-containing pain medications. She reported being 'opioid-free' when contacted at 1 month after her last laser treatment session.

3. Discussion

In 2014, nearly 20,000 deaths were reported in the USA secondary to 'overdosing' with prescription opioid analgesics and in excess of 10 million people in the United States were reportedly using prescription opioids for nonmedical reasons, and approximately 2 million people met diagnostic criteria for a substance use disorder involving prescription opioids [3]. This was the highest number of individuals considered to have an opioid addiction since the late 19th century. Currently, 4 out of 5 individuals initiating heroin use report starting with a prescription opioid. According to Stat News, overdose deaths due to opioids rose 11% in 2015, to 52,404 (https://www.statnews.com/2016/12/09/opoidoverdose-deaths-us). By comparison, the number of people who died in car crashes was 37,757, and gun deaths (including both homicides and suicides), totaled 36,252. Sadly, the public is now paying a huge price for ignoring the warnings regarding opioid use and abuse and we now face the worst addiction crisis America (and the world) has ever observed (Calabresi M. The price of relief: Why America can't kick its painkiller problem. TIME magazine, 2016). In a more recent article in TIME magazine, the author offered a new paradigm for treating opioid addiction, simply giving more drugs (Park A. A new paradigm for opioid addiction: more drugs TIME magazine, October 2016). The 'new' drug treatment which was being described for treating opioid dependency is suboxone (a combination of buprenorphine [a weak partial opioid agonist] and naloxone [an opioid antagonist]). The more aggressive use of opioid-containing compounds to treat both acute and chronic pain has likely contributed to the current opioid crisis [12,13]. Perhaps it is time to consider the use of 'alternative' non-pharmacologic therapies like high intensity cold

laser therapy rather than potentially compounding the problem by giving even more drugs. In the new clinical practice guidelines for the management of back pain published in the Annuals of Internal Medicine [14], the Clinical Guidelines Committee of the American College of Physicians endorsed the use of noninvasive treatments like cold laser therapy for treatment of acute, subacute and chronic low back pain.

LLLT, a form of photobiomodulation therapy, has been studied for over 40 years with mixed results. In 2001, the first FDA-approved cold lasers were approved for clinical use. Laser therapy has been reported to be pro-inflammatory and thereby promote tissue healing and reduce pain. Animal studies suggest that cold lasers promote fibroblast proliferation and the synthesis of Type I and III procollagen mRNA, hasten bone healing, and facilitates wound revascularization. The proposed mechanism of action of laser therapy relates to the ability of damaged cells to absorb the emitted photons and transform the energy into adenosine triphosphate (ATP). Laser stimulation enhances the production of ATP by forming singlet oxygen and reactive oxygen species [15]. The lightabsorbing components of the cell are termed chromophores or photoacceptors and are contained within the mitochondria and cellular membrane. Cell components (e.g., cytochrome c, porphyrins and flavins) also have light absorpbing capacity. The proposed mechanism of LLLT is related to electronic excitation of chromophores in cytochrome c oxidase [unit IV in the mitochondrial respiratory chain] which modulates a redox status of the molecule to enhance cellular functional activity. The chromophores contain both heme and copper centers that absorb light in the near infrared region. The light emitted photons dissociate inhibitory nitric oxide from the cytochrome c oxidase enzyme leading to an increase in electron transport and the mitochondrial membrane potential, thereby enhancing ATP production.

Numerous studies in the peer-reviewed literature have reported that LLLT, and the more recently described high-intensity laser therapy [HILT] with devices like the 42 Watt Phoenix Thera-lase, are effective in reducing both acute and chronic pain. A recent review article by Chow and Armati [16] reported that animal studies using noxious stimuli indicate nociceptor-specific inhibition provides direct evidence of local conduction block, leading to inhibited translation of pain centrally. In addition, there is increasing evidence that laser therapy can disrupt neuronal physiology affecting axonal flow and cytoskeleton organization. The changes produced by laser therapy are completely reversible with no side effects or nerve damage.

After receiving a series of 8–12 HILT sessions with a 42 Watt cold laser to their painful post-surgical area over a 3–4 week period of time, the three opioid-dependent patients described in this Case Report were able to eliminate their use of opioid analgesic medications without experiencing acute withdrawal side effects and were able to resume their normal activities of daily living. On follow-up at 1–2 months after the last laser treatment, all three patients remained essentially 'opioid-free'. These anecdotal findings are subject to potential patient bias and the well-known 'placebo-effect' of a novel pain treatment modality. Therefore, it will be important to conduct a larger-scale prospective, randomized, double-blinded, controlled study to verify these preliminary findings. Our research group is currently conducting a larger scale prospective, randomized clinical trial in this patient population (ClinTrials.gov #NCT02964000, 20162211).

In conclusion, this simple, safe and effective non-invasive HILT with a 42 Watt cold laser can reduce the dependence on oral opioid-containing medications in the post-discharge period after surgery. HILT could also prove to be a highly effective approach to treating other patient populations with chronic pain not responding to non-opioid analgesic medications. More importantly, novel approaches like cold laser therapy may represent a cost-effective alternative to chronic use of opioid analgesics in the future. Finding a reliable non-opioid analgesic alternative for managing subacute and chronic pain could also prove to be extremely valuable in dealing with the current global opioid epidemic.

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Disclosure

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