The case for over-the-counter shortwave therapy: safe and effective devices for pain management

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Practice Points

- Pain is widespread in society and is currently inadequately treated.
- Pharmacological analgesics have limited efficacy and can cause adverse side effects that are more frequent with long-term use.
- Alternative pain therapies that are drug free and have a high safety profile are urgently needed.
- Shortwave electromagnetic therapies have been used for decades for acute and chronic pain.
- Technology advancement, innovation and miniaturization of shortwave devices offer a new, easy-to-use and inexpensive form of this electromagnetic pain therapy.
- Research of these devices is beginning to show how shortwave therapies promote the healing of soft tissue and the mechanisms involved.
- Clinical research has yielded positive results for the use of these devices.
- With increased awareness, shortwave devices can become a home-use pain therapy for many musculoskeletal pain conditions.

SUMMARY Pulsed shortwave diathermy, an electromagnetic therapy, has been in clinical use for acute and chronic musculoskeletal pain for many decades. Innovation, miniaturization and advances in technology have allowed for the development of a new generation of shortwave devices that deliver a localized, low fixed dose of shortwave therapy. Clinical research has shown that these novel shortwave devices can be used safely in order to reduce acute and chronic pain, as well as the need for pain medications. Their ease of use and safety profile make low-dose shortwave devices an attractive alternative, or adjunct therapy, to pharmacological-based pain therapies.

Pain management is a very important healthcare issue, both because of the negative impact pain has on patient quality of life, and also the significant associated healthcare costs involved in pain management. The effect of unresolved pain on quality of life is high, and constant pain

results in a significantly increased risk of depression and suicide [1,2]. Studies have demonstrated the wide prevalence of both acute and chronic pain in society, with estimates of up to 100 million people suffering from chronic pain annually in the USA [3]. The assessment on the costs

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of treating chronic pain in the USA was placed at US\$635 billion annually [3]. This estimate included direct healthcare costs as well as lost productivity, and was indicated by the authors as a conservative estimate.

Pain as a medical issue puts a high demand on healthcare system resources. The current data indicate a shortage of primary care physicians in the USA, which is a problem that is reported to be exacerbated by the increase in federally mandated health insurance coverage, increasing the insured by approximately 30 million [4,5]. With pain being one of the most common reasons for patients to seek medical attention and also consuming a substantial amount of time in pain-related discussions during primary care visits [6], strategies that improve pain management that are safe and cost effective are desperately needed.

Pain management analgesics

Current conventional methods of pain management have a heavy reliance on analgesic drug therapy, and users often show little knowledge or concern of the risks associated with their use [7]. This reliance on drug therapy, often used as a monotherapy, has been proven to be inadequate and, in some instances, has been the cause of adding significant socioeconomic problems [8].

The over-the-counter (OTC) analgesics, acetaminophen and NSAIDs such as ibuprofen, are the most widely used medications. While these medications are generally thought to be safe, there is evidence that adverse side effects, which can be serious, occur especially with long-term use. NSAIDs are associated with a broad range of side effects, including renal toxicity [9], exacerbation of hypertension [10], fluid retention [11], gastrointestinal complications [12,13], cardiovascular events [14] and adverse effects on bone healing [15]. Approximately 107,000 patients are hospitalized annually for related gastrointestinal complications [16] due to the use of NSAIDs, and at least 16,500 NSAID-related deaths occur each year among arthritis patients alone in the USA [17]. This mortality figure does not include OTC NSAID drugs, so it is likely that the actual number is significantly greater. New risks have come to light with OTC pain medications. Epidemiological studies have shown that regular use of the analgesics acetaminophen and ibuprofen increases the risk of hearing loss both in men [18] and women [19] who used these pain medications. In addition, although therapeutic doses of acetaminophen are considered safe, studies suggest

that acetaminophen overdosing is a regular occurrence [20]. At higher doses, acetaminophen can cause fatal liver damage and is responsible for approximately half of all cases of acute liver failure in the USA and the UK [21]. Another study of acetaminophen dosing indicates that hepatic injury linked to acetaminophen use is increasing significantly faster than population growth and acetaminophen product sales, indicating that a growing proportion of consumers are self-dosing acetaminophen beyond the toxic threshold [22]. The bottom line of all of these findings is that the extended use and misuse of OTC pain medications is a significant healthcare problem.

Opioid pain killer use for pain relief has rapidly escalated in the last two decades in the USA, and only recently have clinical, epidemiological and observational studies begun to evaluate their efficacy and effectiveness [23]. The results of these studies are mainly negative [8,24]. The wide adoption of opioids for workplace injury has recently been challenged, and reports suggest that strong opioids delay the return to work and increase compensation insurance costs. Due to their overuse, diversion and abuse, the number of deaths from painkillers quadrupled since 1999 according to federal data, leading the US FDA to consider the restriction of opioid medication use [8,25].

It is now realized that interdisciplinary approaches to pain management, using both pharmacological and nonpharmacological methods, are beneficial for both acute and chronic pain [26–31]. Nonpharmacological methods for treating pain include acupuncture, chiropractic manipulation, behavioral modification and transcutaneous electrical nerve stimulation.

Shortwave electromagnetic therapies

Pulsed shortwave radiofrequency electromagnetic field therapy (termed pulsed electromagnetic field therapy, pulsed shortwave diathermy [PSWD] or pulsed radiofrequency energy therapy) has been shown to be an effective pain therapy that has the potential to impact current treatment options for a number of acute and chronic pain conditions [32–34]. This form of therapy is based on shortwave diathermy (SWD), which uses a shortwave radiofrequency, typically 27.12 MHz, in order to deliver an electromagnetic field into the target soft tissue. Initially, this approach was viewed as a highly effective heat therapy due to preferential

absorption of the energy deep in the body's tissue [35]. Other electrical diathermy therapies that are in clinical use include microwave diathermy and ultrasound diathermy. Microwave diathermy uses radar waves that are of higher frequencies (434 and 915 MHz) than SWD and has a lower depth of penetration. Ultrasound diathermy employs high-frequency acoustic vibrations that are converted into heat in the body.

In the original form, continuous SWD had the potential to cause thermal injury. To prevent excessive heat build-up, the signal was pulsed, which allowed heat to dissipate and the resulting therapy was still found to be therapeutic. This PSWD was labeled a nonthermal therapy as the level of heating was considered to be inadequate for it to be considered a thermal therapy. In the 1970s, the FDA required a sustained tissue heating of 41–45°C to be demonstrated in order for a treatment to be considered a thermal therapy [36], but clearly, PSWD can lead to substantial temperature increases depending on the energy input into the tissue [35]. Therefore, many PSWD treatments that were viewed as nonthermal therapies may actually have a thermal component [37]. SWD and PSWD are in wide use in clinical practice for both acute and chronic pain [38]. However, because of the multiple settings, the potential for thermal injury, and the high cost of many of these SWD and PSWD devices, this form of therapy is still restricted to clinical application by a trained technician. However, development and innovation of this form of electromagnetic field therapy has recently occurred. These new devices use a low, or very low, fixed pulsed signal that is well below the threshold for thermal injury. They often use a battery as a power source and deliver localized treatment with no far-field effects [34,39]. Having a low fixed output at a safe power level negates the danger of thermal injury and consequently the requirement of a trained technician. Therefore, these devices can now become a home-based, economical pain therapy, with the only requirements being the turning on and off of the device and the fixation of this low-powered device onto the target area of the body. To date, no serious side effects have been reported in clinical studies, further suggesting that these devices could be fully developed as home-use pain therapies.

Although these fixed, low-power devices are nonthermal therapies, they may have a very low thermal component as a consequence of the delivered energy. However, the temperature

increases at this level are unlikely to cause the desired effects of heat therapy, namely higher tissue temperatures, which produces vasodilation, increasing the supply of oxygen and nutrients and the elimination of carbon dioxide and metabolic waste. By contrast, heat wrap therapy and the continuous application of heat for 8–12 h has been shown to be therapeutic in a number of studies [40,41]. The temperature increases with heat wraps has been reported to be 2°C at depths of 2 cm [40,42], which are clearly not achieved with low-dose PSWD devices. Therefore, the therapeutic effects of fixed, low-dose PSWD devices are most likely mediated through nonthermal effects.

Clinical studies

Extensive numbers of clinical studies have been performed using nonthermal PSWD over the last five decades for the treatment of acute and chronic pain [32,33]. More recently, clinical studies focusing on pain and edema, using smaller battery-powered devices, have demonstrated positive results for such targets as postoperative edema [43], postoperative pain [39,44,45], plantar fasciitis heel pain [46], pain from osteoarthritis of the knee [47], whiplash neck injury [48,49], delayed-onset muscle soreness [50], soft-tissue injuries [51] and chronic-wound healing [52,53]. These studies reported statistically significant decreases in pain and edema when compared with placebo treatments, confirming that low-power PSWD is an effective pain therapy. Importantly, there have been no reported adverse side effects from these clinical studies. The clinical successes and safety of these devices are very positive indicators that small, home-use, pulsed electromagnetic field devices could be a viable option for pain management.

The data presented in these studies also demonstrates a decreased analgesic medication use. In the postoperative pain study by Rawe *et al.*, significant decreases in narcotic pill use were reported ($p = 0.002$), with patients in the study group using 50% fewer narcotic analgesics while experiencing 50% less pain in the 7-day recovery period [39]. Two further postoperative pain studies reported significant decreases in narcotic medication use during the recovery period, as well as recording decreased pain scores [44,45]. One study reported a significant decrease at day 3 ($p = 0.001$), in the group treated with PSWD relative to the placebo group; this difference continued for the study period of 7 days [44].

The second study reported a significant 2.2-fold reduction in narcotic use in patients treated with PSWD at 48 h after surgery compared with placebo [45]. Other studies have also shown PSWD therapy to reduce the need for pain medication use in both acute and chronic orthopedic pain. During a 12-week study on patients experiencing acute neck pain from whiplash injury, Foley-Nolan *et al.* reported that subjects who received the PSWD therapy were consuming fewer analgesics by week 4 than placebo-controlled subjects [49]. In a study on the effects of PSWD therapy of heel pain from plantar fasciitis, there was a reported significant decline in pain after 7 days and a strong trend towards decreased pain medication use [46].

Device parameters

Clinical studies have used devices with different shortwave radiofrequencies, pulse rates, pulse widths and duty cycles. The different device parameters are shown in Table 1.

The published clinical data have shown that significant reductions in pain can be achieved with various device parameters. The consistency appears to be limited to the pulsed signal and that a shortwave radiofrequency is used by the devices, although different shortwave radiofrequencies have been employed. For example, a direct comparison of different device parameters can be made by looking at the Rawe *et al.* [39] and Heden and Pilla [44] studies. Both were double-blind, randomized and placebo-controlled studies that collected visual analog pain score and medication use data during the first 7 days of postoperative recovery from breast augmentation surgery. The data presented from both of these studies are comparable in that there was a significant decline in postoperative pain scores in the study group compared with the placebo control group, as well as significant reductions in narcotic medication

use during the postoperative study period. This indicates that PSWD can be effective with a range of device parameters.

Biological effects of nonthermal shortwave therapies

Clinical studies have demonstrated PSWD therapy to be an effective pain therapy [32,33]. Moreover, there are indications that PSWD promotes tissue healing by reducing inflammation [34,51]. *In vitro* cell studies using gene arrays have demonstrated that PSWD treatment affects all phases of the wound healing cycle, including the inflammatory phase [54,55]. Expression of the inflammatory cytokine IL-1 β has been shown to be significantly reduced in postoperative wound exudate in a human clinical study [45], as well as in a rat model of traumatic brain injury [56]. Moreover, cell, animal and clinical research has indicated that PSWD therapies elicit a healing response in tissue [51]. In a report by Kao *et al.*, exposing wounds in diabetic mice to PSWD resulted in significantly increased dermal cell proliferation and collagen synthesis [57]. A number of animal studies have also shown improved healing responses to PSWD treatment [56,58,59]. Nonthermal pulsed electromagnetic fields have been reported to induce nitric oxide through a Ca²⁺/calmodulin signaling pathway [60]. Nitric oxide is a potent vasodilator, increasing blood flow and lymphatic drainage, promoting angiogenesis and upregulating growth factors, such as FGF-2. These effects could explain the positive effects on wound healing seen both in animal models and humans. Furthermore, cell studies suggest that the analgesic effect of PSWDs may be due to the increased expression of endogenous opioid peptide, as has been demonstrated *in vitro* by analysis of mRNA expression and opioid peptide levels in a cell culture system exposed to a PSWD [61]. In summary, pulsed shortwave radiofrequency therapies have shown biological responses that support its clinical use for the treatment of pain and soft-tissue healing.

Conclusion & future perspective

Wider use and acceptance of this low-power shortwave technology has been slow in developing, in part due to the position of the FDA, which has maintained these devices in a class III category, a classification that is usually reserved for devices that are life-sustaining, life-supporting and are defined as those that pose a potentially unreasonable risk of illness

Table 1. Radiofrequency, pulse rate, pulse width and duty-cycle parameters of shortwave therapy devices.				
Shortwave radiofrequency (MHz)	Pulse rate/s	Pulse width	Duty cycle (%)	Ref.
27	450	60 μ s	2.7	[48,49]
27	1000	100 μ s	10	[39,43,46,50,52]
27	2	2 ms	0.04	[44,45]
Not specified	71	3.5 ms	25	[53]
6.8	2	7 ms	1.4	[47]
3, 44 and 26	1000 and 900	73 and 100 μ s	10 and 6.5	[51]

or injury. By contrast, the higher-power clinic-based SWD/PSWDs are in a class II category. There are indications that a reclassification may be forthcoming, as a May 2013 adversary panel meeting recommended reclassification, but the discussion and recommendation was limited to postoperative pain and edema [101]. It is possible that high-quality clinical studies may be required by the FDA before giving these low-power devices a new classification. With this noted, regulatory agencies in Canada and the EU, among others, have already classified such devices to be sold OTC.

The current research suggests that PSWD therapy reduces inflammation and promotes tissue healing, a feature that is a powerful argument for the therapy becoming widely available. By contrast, pharmacological approaches to pain management typically mask pain, cause adverse side effects and are contraindicated for a significant proportion of the population [62]. Modern

fixed, low-power PSWDs do not suffer from these drawbacks. The clinical results confirm that PSWD therapy is an effective pain therapy that reduces the requirement of pain medications and, importantly, has shown no reported adverse side effects to date. The clinical success, the positive biological effects on soft tissue and the safety of these devices are very positive indicators that small, home-use PSWDs could be a viable adjunct option for pain management.

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