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Title: Radiofrequency based treatment in therapy-related clinical practice – A narrative review. Part I: Acute conditions

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ABSTRACT

Background: Radiofrequency electromagnetic field (RFEMF or simply RF)-based electrophysical agents have been employed in therapy-related clinical practice for several decades. They are used to reduce pain and inflammation and enhance tissue healing. Although these agents have generally become less popular in contemporary therapy practice, surveys have shown that some of these modalities are still reasonably widely used.

Aim: To review the evidence for the use of non-invasive low frequency RFs (30 kHz–30 MHz) in therapy-related clinical practice.

Methods: All peer reviewed therapy-related clinical studies published in English and concerning low frequency RF were sought. Identified literature was divided into acute and chronic segments based on their clinical area and analysed to assess the volume and scope of current evidence. The studies on acute conditions were reviewed in detail for this paper.

Results: 120 clinical studies were identified, of which 30 related to acute conditions. The majority of studies employed Pulsed Shortwave Therapy (PSWT). Twenty two studies out of 30 were related to conditions of pain and inflammation, seven to tissue healing and one to acute pneumothorax. No studies were identified on frequencies other than shortwave.

Conclusions: Evidence for and against RF-based therapy is available. There is reasonable evidence in support of PSWT to alleviate postoperative pain and promote postoperative wound healing. Evidence for other acute conditions is sparse and conflicting. A general lack of research emphasis in the non-shortwave RF band is evident, with studies on acute conditions almost non-existent. Further and wider research in this area is warranted.

KEY WORDS: Acute conditions, Clinical effects, Electrophysical agents, Non-invasive, Radiofrequency.

INTRODUCTION

Electrophysical agents (EPAs) have established themselves over the years as one of the pillars of therapy practice. They are used by clinicians all over the world to treat a wide variety of conditions. Many of these agents employ some form of electromagnetic fields (EMF), in which 'radiofrequency electromagnetic field' (RFEMF or simply RF) is a major component. Radiofrequency radiations constitute a significant part of the Electromagnetic Spectrum. The Institute of Electrical and Electronics Engineers Inc. (IEEE) define RF as EMF frequencies between 3 kHz–300 GHz.[1,2] This is a broader spectrum compared to the usually referred frequency range of 30 kHz–300 MHz.[2] This paper aims to review the clinical evidence base for RF-based EPAs operating between the frequencies 30 kHz–30 MHz used in physical therapy practice. Research employing radiofrequency higher than 30 MHz is excluded from this review as it is seldom used in current therapy practice.[3]

Though undetectable to the human senses, RF fields are omnipresent and have become an unavoidable part of our lives. Their ranges of applications are innumerable in areas such as communication, industry and healthcare. In medicine and surgery they play a key role in diagnosis, treatment and monitoring of several conditions. The RF literature pertaining to these areas in medical science is substantial, and is beyond the scope of this review. Similarly, the literature base for the biological effects of RF fields is also extensive and a mature scientific discipline with over 60 years of history.[4] Hundreds of studies and numerous reviews have been published analysing the effects, benefits and hazards of RF on the biological systems, either due to intended or due to unintended exposure. Numerous studies describing the theoretical underpinning of RF-induced biological effects are also available.[4-8] Physiological responses to RF-tissue interaction in humans and the mechanisms of actions believed to underpin such responses are well investigated.[4,5,7-9] Besides the extensive literature on the biological effects of high frequency RF (Microwaves: 300 MHz–300 GHz), a considerable proportion of studies deal with smaller RF bands that include the shortwaves (10–100 MHz) and frequencies below the shortwaves (30 kHz–10 MHz). These frequency bands are of particular interest in the therapy arena.[2,10-55]

In physical therapy, the use of RF in EPAs has been reported since the early decades of last century.[56] Mainly three RF modalities were in use, which output contrasting frequencies in the RF spectrum. Longwave diathermy, which employs RF fields of around 0.5–1.0 MHz became obsolete in the 1950s owing to practical limitations and the severe disturbances it caused to communication and broadcasting.[57] Shortwave therapy (SWT) (also known as shortwave diathermy, or SWD) commonly operating at 27.12 MHz and Microwave therapy (also known as microwave diathermy, or MWD) operating at up to 2.45 GHz became more established in practice. However, currently microwave therapy is used infrequently in many countries.[3,58-60] Research pertaining to Microwave therapy and Longwave diathermy are excluded from this review.

Historically, SWT has employed several different frequencies, which are not the same in all countries. In 1947, the Federal Communication Commission of the United States Government assigned three frequencies at the short end of the RF band (40.68 MHz, 27.12 MHz and 13.56 MHz) for the medical use of shortwave in an attempt to regulate the use of high frequency currents in different disciplines.[61] These frequencies used relate to international regulation rather than known effectiveness. Of the three frequencies, 27.12 MHz is the most widely used in current clinical practice.[9]

Shortwave therapy is available in two modes: continuous (CSWT) and pulsed (PSWT). The CSWT has been widely used by clinicians since the 1930s, but has now become less popular and infrequently used in the western world.[3,62] There is in fact an evidence base to support the use of CSWT, so the diminishing popularity is partly linked to a 'fashionable shift' rather than the evidence base *per se*.[9] In contrast, PSWT, which was developed in the 1940s and has since become the more popular delivery option, is in use among about 11% of outpatient clinics in the UK.[3,62,63] In the literature several synonymous terms can also be found alongside PSWT, such as pulsed electromagnetic energy (PEME), pulsed electromagnetic field (PEMF), pulsed high frequency electromagnetic energy (PHFE) or pulsed radiofrequency energy (PRFE) although the majority of such devices employ RF at 27.12 MHz. This is because some of the device manufacturers used such terms instead of the more generic PSWT. Throughout this review the authors will use the term pulsed shortwave therapy (PSWT) for consistency.

In addition to these three modalities, devices operating at significantly lower RF ranges (below 1 MHz) have also been reported and have become commercially available. Nonetheless, the research in this area is sparse. The authors of this review identified a limited number of articles pertaining to this area.[46-48,50,64-77] The current literature (published in English) indicates that the RF used in therapy-related clinical practice is predominantly in the SWT band, and largely limited to PSWT as a delivery mode.[3,9,62,78-80]

Although several authors have reviewed the therapeutic effects of SWT as they are applied to various specific conditions,[56,62,79,81-83] none covers all the therapy-related clinical literature in this frequency spectrum. No similar reviews are available on the clinical studies that have employed RF below the shortwave frequencies. Furthermore, only a limited number of studies appear in the majority of the reviews identified, owing to their stringent inclusion criteria.

This paper aims to review all therapy-related clinical studies conducted on human patients covering the frequency range of 30 kHz–30 MHz and discuss the studies on acute conditions in detail. In addition, the authors identified several studies conducted on laboratory animals evaluating the effects of RF on experimentally-induced acute conditions. Although these studies are beyond the primary remit of this review, it may be of interest to illustrate some of the key issues in relation to the clinical studies. Hence, the RF studies performed on animals within the referred frequency range will be discussed here prior to the clinical literature.

Experimental studies on animals

Four animal studies on the effects of SWT on healing of acute wounds were identified; two on healing of skeletal muscle injuries[14,15] and one each on bone injury[51] and skin wound.[16] One study each investigated the resolution of haematomas[17] and arthritis[20] with the application of PSWT.

In 1951, Hutchison[51] conducted two experiments on adult dogs with bilateral tibial grafts and adult male rabbits with radial fracture. Conventional CSWT was used in both experiments at a ‘mild thermal’ dose (20 minutes twice daily). In both experiments, the authors concluded that CSWT ‘significantly delayed’ healing of fractures and bone grafts compared to the untreated control group animals. These findings are contrary to the findings of the clinical study by Cameron[84] (discussed later). Similarly, rabbits with skin cuts and guinea pigs with third degree skin burns were subjected to PSWT (38 W MP for 10 minutes once daily) by Constable and colleagues.[16] Unlike the results from the clinical studies, PSWT did not improve wound healing in either of the animal groups.

Calf muscle injury in rabbits induced by injecting 'xylocaine' was treated by PSWT (dose parameters not fully reported) for 20 minutes twice daily for either eight or 16 days in the study by Brown and Baker.[15] While the 8-day treatment failed to influence muscle healing, a trend towards enhanced healing was observed with a 16-day treatment programme. In another study on the effects of CSWT (five minutes daily for seven days at an intensity producing 'bearable heat') on induced biceps femoris muscle injury in adult dogs, Bansal and colleagues[14] demonstrated early maturation of the collagen fibres at the healing site as well as regeneration of the injured muscle fibres. It is unclear how the authors were able to adjust the dose as 'bearable heat' in an animal model. Both the above studies were comparable to the clinical studies on postoperative wound healing (discussed later), though the results were conflicting.

Fenn[17] reported the effects of PSWT (30 minutes twice daily for 9 days; dose parameters not fully reported) on experimental haematomas induced in the ears of 30 male rabbits. Fifteen actively treated animals demonstrated a significantly faster resolution of the haematoma compared to another group treated with a placebo. Similarly, Nadasdi[20] used PSWT (10 minutes for up to four times; dose parameters not fully reported) in rats with experimentally induced arthritis of the tibio-calcaneal joint. Significant inhibition of arthritis was obtained with PSWT when compared to the non-treated group. In another study, Silverman[40] showed that either CSWT or PSWT was no different to a control or a placebo condition in treating infected mice. Mice inoculated with pneumococcus bacterial colonies were irradiated for 15 minutes twice daily for three days or till the animals died. The treatment failed to improve the outcome. No clinically relevant human studies were identified under any of the above three conditions.

METHODS

The authors carried out electronic literature searches as well as hand searches of print journals to identify relevant articles. Electronic searches were carried out using the online bibliographic databases PubMed, Scopus, ISI Web of Science and CINAHL Plus. Google Scholar was also used as an additional source. Articles were also identified by further hand searches of the reference lists. References were managed using the EndNote X6 (Thomson Reuters) software package.

Primary searches carried out to identify relevant articles covered publications from all the years to date (January 2015). Key search words used were "Radiofrequency", "RF", "Electromagnet*", "EMF", "Shortwave", "SW" and "Diathermy", and alternate forms and combinations of these keywords. Further filtering was performed using additional search words "Biological", "Clinical", "Physiological" or "Therapeutic", and "effects". All articles dealing with the RF frequency range of 30 kHz–30 MHz were retained as a 'primary pool'. This pool contained clinical, non-clinical, animal research, theoretical as well as review articles irrespective of the language, study type or methodology.

From among the clinical studies in this pool, all therapy-related clinical studies published in English and conducted solely on human patient(s) employing a non-invasive and non-ablative methodology were selected for the review. Studies published in languages other than English, or conducted in healthy human subjects or in animals were excluded. Additionally, studies needed to be conducted on patients *in vivo* pertaining to any clinical area within the realm of therapy and rehabilitation. As identified, some animal studies on RF have already been discussed in the introduction to illustrate some key issues. The inclusion/exclusion criteria stated above reflect the all-inclusive methodological approach the authors have followed for the purpose of this review. This approach is dissimilar to that of a systematic review and does not exclude studies based on their methodological design and/or quality as would be the norm in a systematic review. It is not a novel approach and several examples of such reviews can be found in contemporary therapy literature.[85-88]

The full-texts of the included studies were obtained. The studies were stratified on the basis of the frequency of RF used (shortwave, non-shortwave), the study design (clinical trial, cohort study, case series), the duration of clinical condition (acute, chronic) and the clinical application category [pain and inflammation, tissue healing, others (all other less reported conditions, e.g. – acute pneumothorax)]. For the purpose of this review 'acute' is considered as conditions not older than 4–6 weeks and 'chronic' as conditions older than six weeks. The authors understand that it is problematic to divide studies in to distinct categories based on the duration of condition or clinical application category as conditions may overlap to a varied extent. However, based on examples available from the existing literature[89,90] the terms 'acute' and 'chronic' are not explicitly defined and any duration used for classifications have been based merely on personal opinion or anecdotal evidence.[91]

The studies employing RF devices generating 10–30 MHz were considered as shortwave studies, and those employing 30 kHz–10 MHz as non-shortwave studies. The methodological quality of the studies were screened using the Cochrane risk of bias assessment tool[92] (where appropriate), and scored based on the checklist proposed by Downs and Black[93] for randomised and non-randomised studies. This checklist is a valid tool[94] containing 27 items concerning the quality of reporting, validity, bias and statistical power of the studies (maximum score of 32; higher the score better the quality). Over the years, several authors have used modified versions of this checklist, mainly by simplifying the 'item 27' (originally scored 0–5) that concerns statistical power.[95,96] A similar modified version, scoring item 27 as either ‘zero’ (insufficient power) or ‘one’ (sufficient power) was used in this review. Hence, the maximum score that could be obtained by a study was 28.

RESULTS

The flow of studies through the review is given in Figure 1. A 'primary pool' of 588 articles within the frequency range 30 kHz–30 MHz was generated after the initial screening. Within this, 555 articles related to shortwave frequencies and 45 to non-shortwave frequencies. Some (12 articles) covered frequency ranges that overlapped these nominal groupings.

From the primary pool 120 clinical studies met the inclusion criteria for the narrative review. Among this, 112 were shortwave studies and eight were non-shortwave studies. Two potentially suitable studies employing shortwave were excluded as they had no proper abstracts and their full-texts were unavailable through our resources.[97,98] Eighty nine studies were conducted on conditions relating to pain and inflammation and 23 on conditions relating to tissue healing. A further eight studies were classed as 'others' and related to a mixture of conditions that were relatively less reported (e.g. Acute pneumothorax). However, as identified, the authors recognise that it is problematic to classify studies into such distinct clinical categories, given that they may overlap to a varied extent. Clearly there was potential overlap between studies that considered pain and inflammation and that considered tissue healing. For the purpose of this review, the allocation of a particular paper to a group was based on the primary outcome(s) as identified by their authors.

A total of 30 studies investigated acute clinical conditions and 90 investigated chronic clinical conditions. Although the overall results of the literature review have been presented here, this paper will discuss only the 30 studies on acute conditions. The studies on chronic conditions will be discussed in a future separate paper. The full texts were available for all the studies discussed here except for two.[99,100]

Insert Figure 1 here

Insert Table 1 here

DISCUSSION OF RESULTS

The authors of this review identified 30 studies that investigated the effects of RF on acute therapy-related clinical conditions. All studies used devices delivering RF energy at the shortwave frequency of 27.12 MHz. Overall, 22 studies dealt with conditions pertaining to pain and inflammation,[101-122] seven to tissue healing[84,99,100,123-126] and one study to other conditions[127] (acute pneumothorax). The studies are considered in detail in the following sections. Their key characteristics and Downs and Black scores are briefed in Table 1.

STUDIES ON PAIN AND INFLAMMATION

Studies published on the effects of RF on various acute conditions that give rise to pain and inflammation formed the largest group. Nine clinical trials were identified on postoperative pain,[101,102,106,111,112,119-122] six on ankle injuries,[103,105,107,110,113,117] two on fracture pain,[116,118] and one each on hand injuries,[109] acute low back pain,[108] whiplash injuries[115] and pelvic trauma in women.[114] Besides, there was one case series on RF therapy of soft-tissue injuries in professional footballers.[104]

Postoperative pain

In 1968, Kaplan and Weinstock[101] achieved significant reduction in postoperative pain, oedema and erythema using PSWT on patients who had undergone foot surgery (100 participants divided in to either active or placebo groups). The participants received PSWT for 10–15 minutes twice daily to the operative site as well as to the epigastrium. Later, Aronofsky[102] achieved comparable results using a similar dose of PSWT on 90 patients (three groups of 30 each) who had undergone oral and dental surgical procedures. The active group(s) received treatment over the surgical site for two sessions (15 & 10 minutes) pre-operatively and/or 10 minutes postoperatively. This trial, however, had several methodological limitations and lacked objective outcome measures.

In contrast, PSWT (10 minutes once daily) delivered over the surgical sites of patients who had undergone dental surgery failed to improve pain symptoms in the study by Hutchinson and colleagues.[106] Forty one actively-treated patients were compared to the same number of patients who received a placebo. In agreement with Kaplan and Weinstock,[101] in the study by Santiesteban and Grant[111] two sessions of PSWT (30 minutes each) on the day of surgery significantly reduced NSAIDs intake (both the number and strength of doses) and the length of hospital stay among 50 patients who underwent foot surgery (two groups of 25 each). However, it is unclear whether the groups were equal at baseline. In another study, no benefit was obtained from 'non-thermal' PSWT (15 minutes twice daily for two days) in patients who had undergone inguinal herniorrhaphy.[112] One may argue though, that the intensity of RF applied at a mean power of 0.02 W (Table 1) with a short intervention period may only be as good as placebo.[27]

There appears to be a chronological gap in this category after which four randomised controlled trials (RCTs) have been reported recently on small wearable type RF generators. Two studies[119,121] on patients who had undergone breast augmentation surgery showed beneficial effects of such therapy in terms of reduced postoperative pain and reduced consumption of pain medication. In the first study by Heden and Pilla,[119] PSWT was delivered for 30 minutes 3–6 times daily for the first six days postoperatively; and then twice daily until the follow-up visit on day seven. In the second study by Rawe and colleagues,[121] PSWT was delivered continuously from postoperative day one till day seven. Both studies were small and did not employ true control groups. In another small study, Rohde and colleagues[120] used a similar device and treatment regimen as Heden and Pilla,[119] but in patients who had undergone breast reduction surgery. They demonstrated a three-fold drop in the pain scores of 12 actively treated patients compared to 12 placebo group patients. In this study, a reduction in interleukin 1-β levels of the wound exudate was also demonstrated, claiming an RF-induced modulation of the wound healing process. In a further study investigating the benefits of wearable PSWT devices,[122] 57 patients who underwent bilateral upper blepharoplasty and received either an active or a placebo PSWT device to their eyes did not report any difference between the two in terms of postoperative pain, oedema or ecchymosis. However, there was a statistically significant reduction in physician-graded erythema in actively treated eyes compared to the placebo. The devices (active for one eye and placebo for the other) were worn for varying durations for up to one week postoperatively. However, both active and placebo groups also used cold patches where required, but this was not controlled or accounted for in the final analysis.

To conclude, among the studies that investigated the effects of RF on postoperative pain conditions, the majority have claimed significant benefits from RF therapy. All studies started the RF intervention either pre-operatively or immediately postoperatively. It may be noted (Table 1) that the studies that reported no benefit from RF therapy have generally employed a lower dose and/or overall duration of intervention. However, because of the varied nature of dosage parameters used by the authors any potential range of ideal doses could not be identified. The results of the studies in this group need to be considered against their overall methodological quality, several of which were problematic, especially the earlier studies. The majority did not feature a true control group and failed to demonstrate sufficient statistical power or equivalence between the groups at baseline, which may serve to weaken their overall impact. Treatment of the epigastric area (over the liver) was employed by some earlier studies, as preceding studies performed on healthy adults[37,128] had reported that it increased peripheral circulation. However, this practice became less popular in later years.

Acute ankle injuries

In an RCT by Wilson,[103] sixty minutes of PSWT administered for three consecutive days was shown to reduce pain and disability among patients (20 active, 20 placebo) who sustained acute ankle inversion injuries. The author obtained comparable results in a further study[105] that also employed CSWT and where methods similar to the first study were used. Conversely, Pasila and colleagues[107] failed to demonstrate any significant difference in pain and swelling among 300 patients with recent ankle and foot injuries in a much larger study. There were two active groups receiving two types of PSWT, and one placebo group. Although the intervention in this study was similar to the study by Wilson,[103] the PSWT dose was much shorter (20 minutes daily for three days). Similarly, Barker and colleagues[110] also failed to demonstrate any evidence in support of PSWT for acute ankle injuries (45 minutes each for three days) compared to a placebo. The study included a total of 73 participants, but experienced high drop-out rates at the follow-up.

McGill,[113] who studied 37 patients (PSWT and placebo groups, no true control group) with lateral ligament sprain of the ankle, further reported that PSWT (three 15-minute sessions) was not beneficial. The latest study identified in this category was published by Pennington and colleagues[117] 20 years ago. Fifty participants who had suffered grade I–II ankle sprain were treated with PSWT or placebo for one session, for a total of 70 minutes given in multiple positions (30 minutes medially and 30 minutes laterally to the ankle joint; 10 minutes to the epigastrium). Significant reduction in ankle oedema was noted in the active group compared to the placebo group.

On the whole, the evidence in this group was equivocal. The RF intervention commenced within 36 hours after the injury in all the studies except in two studies[107,117] (within 3–4 days).[107,117] In terms of trial quality, both groups of studies, which were either against or in favour of using RF, had several methodological shortcomings including a lack of sufficient statistical power, lack of baseline equivalence between the groups, lack of follow-up and high drop-out rates. Many studies did not report dosage parameters adequately and for others the doses were varied (Table 1). However, where reported it may be noted that similar to the studies on postoperative pain, the studies on ankle injuries that reported no benefit from RF therapy employed a lower dose and/or overall duration of intervention.

Fracture pain

Only two studies were identified in this category. The first study published by Livesley and colleagues[116] investigated the effects of PSWT (30 minutes daily for 10 consecutive days) in the management of fracture of the neck of humerus. Forty eight patients (22 active, 26 placebo) were treated and followed-up for up to six months. No significant difference was found between the groups either for pain or for functional scores at any stage. In the second study by Buzzard and colleagues,[118] twenty patients presented to a trauma unit with unilateral calcaneal fractures were treated either by PSWT (15 minutes twice daily for five days) or by ice therapy (‘Cryocuff’ for 20 minutes, six times a day for five days). Daily measurements of swelling and ankle ROM showed significant improvement in both groups with no significant difference between the groups. Like several previously discussed studies, both trials had limited statistical power, lacked a true control group and did not demonstrate sufficient equivalence between the groups at baseline. While the dosage parameters were inadequately reported in the first study, the second employed a very low mean dose of PSWT (Table 1), which arguably was too low to be clinically effective.

Other acute conditions with pain

A case series on the PSWT management of soft tissue injuries in professional footballers was published by Wright in 1973.[104] A rapid reduction in intra-muscular haematoma was reported with repeated daily PSWT for up to a week. In a later clinical trial by Nwuga,[108] 51 female patients suffering from acute low back pain were treated with either CSWT (20 minutes thrice weekly) or spinal manipulation, for up to six weeks. The study showed that manipulation was superior to CSWT in terms of improving the spinal and pelvic range of movement (ROM). The study, however, did not objectively assess pain or outcomes of functional quality of life of the participants. Also, there were no follow-up assessments. The generalizability of these findings is limited, as only female subjects were included.

Similarly, 414 women recovering from pelvic trauma (sustained during childbirth) who were studied in four groups (PSWT, ultrasound, placebo-PSWT or placebo-ultrasound) by Grant and colleagues[114] did not demonstrate any significant difference between the groups at the end of treatment. The PSWT treatment was given for 10 minutes daily for three days. Although this was a large trial with adequate statistical power, a true control group was absent and the outcome measures employed were predominantly subjective in nature. In another large trial by Barclay and colleagues[109] on 230 patients who had sustained hand injuries, 114 active group participants who were treated by PSWT (30 minutes twice daily for up to seven days) showed marked reduction in pain, swelling and disability over 116 control group participants. Similarly, in a well-designed study by Foley-Nolan and colleagues,[115] 20 patients who had sustained acute whiplash injuries treated with PSWT (RF generating collar worn for eight hours daily for 12 weeks) reported significant improvement in pain compared 20 placebo-treated patients.

This group contained a mixture of studies, which have mostly reported favourable results for the use of PSWT. As with other groups of studies on pain and inflammation, methodological shortcomings (absence of true control group, lack of follow-up, subjectivity of outcome measures) and lack of adequate reporting (statistical power, dose parameters) were apparent.

STUDIES ON TISSUE HEALING

Out of the seven studies included in this category, five were on healing of postoperative wounds,[99,100,123-125] and one each on bone healing,[84] and healing of lacerated wounds of the lower limb.[126] All studies used devices delivering RF energy at a frequency of 27.12 MHz.

Postoperative wound healing

Five studies examined the effects of SWT on healing of postoperative wounds, of which four were clinical trials[99,100,123,124] and one cohort study.[125] In a double-blinded RCT Bentall and Eckstein[100] claimed that the rate of bruise resolution in boys who underwent orchidopexy operation was significantly better when PSWT (20 minutes locally to the operated site; 10 minutes to the epigastrium three times a day for four days) was added to the treatment programme. Rhodes[124] claimed that 247 postoperative patients who had undergone oral surgery showed accelerated recovery compared to 254 controls, with daily exposure to PSWT (30 minutes locally and 20 minutes over the liver).

In a further RCT by Goldin and colleagues,[123] 29 patients who had undergone a skin grafting procedure and subsequently received PSWT showed improved healing to the donor site compared to 38 patients who received a placebo intervention. One treatment lasting 30 minutes was given to the donor site at the time of pre-medication and four times daily postoperatively, for seven days. Later in a pilot study of 21 cases of blepharoplasty, Nicolle and Bentall[125] showed enhanced wound healing when treated postoperatively with a wearable PSWT device (worn for 24 hours continuously postoperatively). Similarly, Arghiropol and colleagues[99] suggested that postoperative patients treated locally over the operated site by PSWT (15 minutes) and over the liver (30 minutes) presented higher blood plasma levels of fibronectin, which correlated well with a clear improvement of the wound healing processes.

None of the trials discussed in this category employed both placebo and control conditions and many failed to establish adequate equivalence between the study groups at baseline. All studies started the RF intervention either pre-operatively or immediately postoperatively. Similar to the studies on postoperative pain, the dosage parameters where reported remained varied, hence any commonalities could not be drawn.

Other studies on tissue healing

A study by Cameron[84] reported favourable results with PSWT in bone and soft tissue injuries. In a mixed design research project containing three separate studies, a total of 646 surgical and non-surgical orthopaedic patients benefitted from PSWT (20 minutes over the liver and 20 minutes over the wound, twice daily for four days). However, despite the presence of a large sample, the study lacked a properly randomised methodological design, and no standardised outcome measures were used for assessment. In 1991, Muirhead and colleagues[126] reported an RCT of 129 patients who had sustained lower limb injuries (pre-tibial lacerations). Sixty six patients in the active group received PSWT (10 minutes three times a week) in addition to standard wound dressing. Contrary to the studies discussed previously, there was no evidence of accelerated wound healing. This study failed to reach adequate statistical power and had a high participant drop-out rate, which was not accounted for in the analysis.

STUDIES ON OTHER APPLICATIONS

While the vast majority of RF research in the acute clinical area is centred on applications for reducing pain and inflammation, and some others for tissue healing, only one study was identified, which investigated the effects of RF on other acute conditions. In a blinded RCT, Ma and colleagues[127] studied 22 patients with pneumothoraces of less than 30% volume, in two groups. One group received a daily dose of CSWT for 25 minutes (at an intensity causing ‘just perceptible warmth’). The control group participants were kept under observation with only bed rest. The time to lung re-expansion was found to be significantly shorter in the CSWT group compared to the bed rest group (3–12.5 days and 8–17 days respectively). The study, however, is unlikely to have had sufficient statistical power (unreported) with only 11 subjects per treatment arm. Although this trial was published in 1997 and the results were encouraging, no further studies on this condition have been reported since.

CONCLUSIONS

Evidence in favour of and against RF-based therapy for acute clinical conditions is available within the referred frequency range. Although the review did not employ a cut-off (Downs and Black) score for the methodological quality, the conclusions drawn here are based primarily on the results reported by well-designed studies and the overall weightage of the available evidence.

The majority of research is centred on PSWT, with only very few studies conducted on CSWT. No studies were identified in the non-shortwave RF range. While the bulk of studies that investigated the effects of PSWT on postoperative pain conditions have reported its significant benefits, the studies on acute ankle injuries have shown mixed results. As identified, there were dose-dependency issues in both these groups. There were limited numbers of studies published on the effects of RF-based therapy for other acute conditions giving rise to pain.

Studies have also supported the use of PSWT to promote postoperative wound healing. As identified, there was potential overlap between the ‘postoperative pain’ and ‘postoperative wound healing’ groups. Hence, on the whole there is reasonable evidence to support the use of PSWT for postoperative pain and postoperative wound healing. Since the studies employed a wide range of dosage parameters (where reported), it has not been possible to identify and recommend an ideal dosage range for the studied conditions based on their reported results alone. Evidence for other acute conditions giving rise to pain, concerning tissue healing or other less reported conditions is sparse and conflicting.

The evidence reported in this review may only be considered against the overall quality of the included studies, which was mixed. An apparent lack of robustness and integrity in the methodological designs, and infrequent reporting of the RF dosage parameters, outcomes and statistical analysis made the assessment of results problematic for many studies. A lack of consistency in reporting was particularly evident in the earlier studies. Where doses were reported, the rationale for selection was unclear. Additionally, poor baseline equivalence between study groups was often evident; and participant drop-outs, which were sometimes high were not accounted for in the final analysis (no intention-to-treat analysis) as would be the norm in current publications. Owing to the varied nature of methods, outcomes and interventions of the included studies, it has not been possible to compare and draw any commonalities between them.

Although RF-based therapy has been in use for almost a century, therapy-related clinical research in this area is still scant, with only limited number of studies published on acute clinical conditions. The types of such clinical conditions studied for the effects of RF-based therapy are even more limited. Clearly there is a need for further research in this area. Even though this review considered studies from the frequency of 30 kHz and above, no studies on acute conditions employing RF below the shortwave frequency of 27.12 MHz were identified. On the whole, a lack of research in the non-shortwave RF band is evident, with studies on acute conditions almost non-existent. This warrants research emphasis in this area especially since devices delivering non-shortwave RF have long been used in therapy.

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Figure 1: Flow of articles through the review.

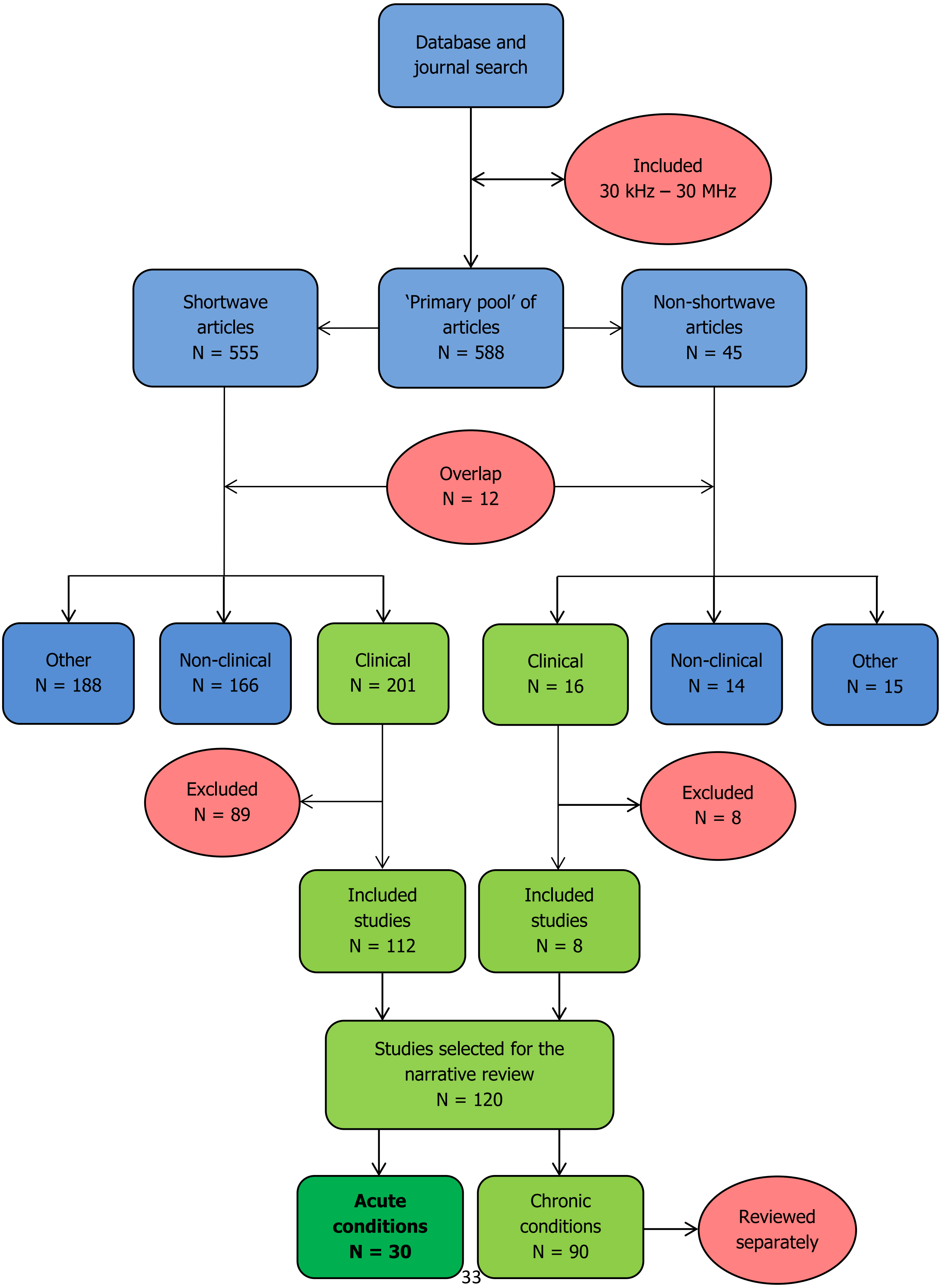

Table 1: Key characteristics of the studies on acute conditions.

Study	Diagnostic category	Outcomes measured	Study type, sample size and number of groups	Type of RF used	RF dose parameters					Number and duration of sessions	Did RF improve the outcomes significantly?	Downs and Black score (out of 28)
					CSWT Power (W)	PSWT						
						PP (W)	PD (µs)	PRR (pps)	MP (W)			
Kaplan and Weinstock 1968[101]	Foot surgery	Pain, oedema and erythema	RCT; 100 subjects; 2 groups	PSWT		975/ NR	65	600/ 400	38/ NR	≥7 (over 3 days); 10–15 min/session	Yes	15
Aronofsky 1971[102]	Dental surgery	Pain, inflammation and 'healing rate'	Non-RCT; 90 subjects; 3 groups	PSWT		975	65	600	38	≤6 (over 4 days); 10–15 min/session	Yes	9
Hutchison et al. 1978[106]	Dental surgery	Pain, swelling, trismus, analgesic intake and complications	RCT; 82 subjects; 2 groups	PSWT		NR	65	500	NR	5 (over 4 days); 10 min/session	No	12
Santiesteban and Grant 1985[111]	Foot surgery	Analgesic intake and hospital stay	RCT; 50 subjects; 2 groups	PSWT		120	95	700	8	2 (over 1 day); 30 min/session	Yes	16
Reed et al. 1987[112]	Inguinal herniorrhaphy surgery	Pain and analgesic intake	RCT; 43 subjects; 2 groups	PSWT		1	60	320	0.02	≥4 (over 2 days); 15 min/session	No	17
Heden and Pilla 2008[119]	Breast augmentation surgery	Pain and analgesic intake	RCT; 42 subjects; 3 groups	PSWT		2	2000	2	0.01	31 (over 8 days); 30 min/session	Yes	22
Rohde et al. 2010[120]	Breast reduction surgery	Pain, interleukin 1-β level and analgesic intake	RCT; 24 subjects; 2 groups	PSWT		2	2000	2	0.01	12 (over 2 days); 20 min/session	Yes	23
Rawe et al. 2012[121]	Breast augmentation surgery	Pain and analgesic intake	RCT; 18 subjects; 2 groups	PSWT		98×10^{-4}	100	1000	0.001	7 (over 7 days); 24 hours/session	Yes	22

Czyz et al. 2012[122]	Blepharoplasty surgery	Pain, oedema and ecchymosis	RCT; 57 subjects; 2 groups	PSWT		9.4×10^{-9}	10^{5}	1000	0.94×10^{-6}	4–10 (over 4–10 days); ≈7 hours/session	No	21
Wilson 1972[103]	Ankle soft tissue injury	Pain, swelling and disability	Non-RCT; 40 subjects; 2 groups	PSWT		975	65	600	38	3 (over 3 days); 60 min/session	Yes	16
Wilson 1974[105]	Ankle soft tissue injury	Pain, swelling and disability	Non-RCT; 40 subjects; 2 groups	CSWT/ PSWT	NR	975	65	600	38	3 (over 3 days); 30/60 min/session	Yes	14
Pasila et al. 1978[107]	Ankle and foot soft tissue injuries	Ankle strength, range of movement, swelling and gait	RCT; 300 subjects; 3 groups	PSWT		NR	NR	NR	38/40	3 (over 3 days); 20 min/session	No	13
Barker et al. 1985[110]	Ankle soft tissue injury	Pain, swelling, range of movement and gait	RCT; 73 subjects; 2 groups	PSWT		NR	65	640	NR	3 (over 3 days); 45 min/session	No	17
McGill 1988[113]	Ankle soft tissue injury	Pain and swelling	RCT; 37 subjects; 2 groups	PSWT		600	400	82	19.6	3 (over 3 days); 15 min/session	No	16
Pennington et al. 1993[117]	Ankle soft tissue injury	Pain and swelling	RCT; 50 subjects; 2 groups	PSWT		NR	NR	NR	NR	1 (over 1 day); 70 min/session	Yes	18
Wright 1973[104]	Lower limb soft tissue injuries	Pain, swelling and ‘return to function’	Case series; 40 subjects	PSWT		NR	NR	NR	NR	≤8 (over ≈7 days); NR	Yes	5
Nwuga 1982[108]	Lumbar intervertebral disc prolapse	Lumbar range of movement	Non-RCT; 51 subjects; 2 groups	CSWT	NR					≤18 (over ≈6 weeks); 20 min/session	No	14
Barclay et al. 1983[109]	Hand soft tissue injuries	Pain, swelling and disability	RCT; 230 subjects; 2 groups	PSWT		975	65	600	38	≤14 (over ≈7 days); 30 min/session	Yes	17
Grant et al. 1989[114]	Perineal trauma post childbirth	Pain, oedema, bruising, haemorrhoids and analgesic intake	RCT; 414 subjects; 3 groups	PSWT		NR	65	100	NR	3 (over 2 days); 10 min/session	No	24

Foley-Nolan et al. 1992[115]	Whiplash injuries	Pain, range of movement and analgesic intake	RCT; 40 subjects; 2 groups	PSWT		NR	60	450	NR	84 (over 12 weeks); 8 hours/session	Yes	21
Livesley et al. 1992[116]	Shoulder fracture	Pain, muscle bulk, muscle strength, range of movement and joint function	RCT; 48 subjects; 2 groups	PSWT		300	NR	35	NR	10 (over ≈14 days); 30 min/session	No	20
Buzzard et al. 2003[118]	Calcaneal fracture	Swelling and ankle range of movement	Non-RCT; 20 subjects; 2 groups	PSWT		35	200	26	0.18	10 (over 5 days); 15 min/session	Yes, but not better than ice therapy	17
Rhodes 1981[124]	Oral surgery	Bleeding, healing time, return to function, pain and oedema	Non-RCT; 501 subjects; 2 groups	PSWT		975	65	600/ 400	38/ 25.3	NR adequately; 40 min/session	Yes	8
Goldin et al. 1981[123]	Skin graft wounds	Rate of healing and degree of pain	RCT; 67 subjects; 2 groups	PSWT		975	65	400	25.3	29 (over 7 days); 30 min/session	Yes	12
Nicolle et al. 1982[125]	Blepharoplasty surgery	Oedema and ecchymosis	Case series; 21 subjects	PSWT		NR	100	1000	NR	1 (over I day); 24 hours/session	Yes	12
Bentall and Eckstein 1975[100]	Orchidopexy surgery	Oedema and healing rate	RCT; 100 subjects; 2 groups	PSWT		NR	65	500	NR	12 (over 4 days); 30 min/session	Yes	NA
Arghiropol et al. 1992[99]	Postoperative wound	Healing rate and plasma fibronectin concentration	NA	PSWT		NR/ 975	65	400/ 600	NR/ 38	NA; 45 min/session	Yes	NA
Cameron 1964[84]	Surgical and non-surgical wounds	Rate of healing and hospital stay	Non-RCT; 646 subjects (3 studies with 2 groups each)	PSWT		NR	65	400	NR	8 (over 4 days); 40 min/session	Yes	5
Muirhead et al. 1991[126]	Pre-tibial laceration	Size of wound and healing time	RCT; 129 subjects; 2 groups	PSWT		NR	400	20–46	NR	≤18 (over ≈6 weeks); 10 min/session	No	16
Ma et al. 1997[127]	Pneumothorax	Time to lung re-expansion	RCT; 22 subjects; 2 groups	CSWT	NR					≤13 (over ≈13 days); 25 min/session	Yes	18

RCT – Randomised Controlled Trial; RF – Radiofrequency; CSWT – Continuous Shortwave Therapy; PSWT – Pulsed Shortwave Therapy; PP – Peak power; PD – Pulse duration; PRR – Pulse repetition rate; MP – Mean power; NR – Not reported; NA – Not available to the authors; W – Watts; µs – Microseconds; pps – Pulses per second; min – Minutes.