Effect of Electromagnetic Field on Wound Healing in Venous Ulcers (A Systematic Review)

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Abstract: Objective: the aim of this work was to systematically review this studies which assess the effect of electromagnetic field on wound healing in venous ulcers. Methods: Systematic review of all published studies with all research designs expect expert opinions. A search was made in Medicine, Cochrane library. PED. And Google scholar. Intervention different types of electromagnetic field performed by the physical therapy in wounded patients in venous ulcers outcomes measure wound healing. Results: only 3 studies met the inclusion Criteria, there was conflicting evidence on whether electromagnetic field can accelerate the wound healing. The three studies show significant acceleration of wound healing. Conclusion: the current level of evidence to support the effectiveness of electromagnetic filed on wound healing in venous ulcers was good.

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Key Words: Systematic Review, Electromagnetic Review, Electromagnetic Field, Wound Healing and Venous Ulcers.

Introduction

A systematic review is the application of scientific strategies that limit bias by the systematic assembly, critical appraisal and synthesis of all relevant studies on a specific topic **(Manchikanti, 2008)**.

A Systematic review is a "study of studies". All relevant researches are Analyzed in an effort to determine the overall evidence for an intervention. A Systematic review is a literature review focused on a single clear question which tries to identify, select and appraise all high quality research evidence relevant to that question then makes assessment of the included studies and synthesis of Findings and interpretation. Systematic reviews are generated to answer specific, offen narrow clinical question in depth **(Garg et al., 2008).**

Decision making is the process by which evidence is or not applied to Practice. The statement "evidence alone does not make decisions, people do" reflects the integral role of the therapist in translation of evidence to practice. Therapists make decisions on complex issues related to examination, prognosis, expected outcomes, the plan of care, and coordination of care on a daily basis **(Haynes et al., 2002 and Guyatt et al., 2000).**

The importance of randomized controlled trial comes from several facts

•It is the surest method to prove cause _effect relationship.

•It has the least biased design; however, a badly design or conducted RCT can be hazardous to medical practice; medical practitioners and patients as much as good one is useful to them.

•It generates the highest level of evidence especially in questions related to interventions and therapy **(Attia, 1999).**

Appraisal of the evidence includes assessment of the relevance and validity of the evidence (clinical applicability) and finally the evidence is integrated with clinical experience and patient values before applying it to the patient **(Attia, 1999).**

Evidence based medicine is needed to improve quality of health care. A body of evidence regarding safety, effectiveness, appropriate indications, cost-effectiveness, and other attributes of medical care are demanded **(Manchikanti, 2008).**

We live in the information age; the number of published studies in the biomedical literature has dramatically increased. Because even highly cited trials may be challenged over time, clinical decision-making requires ongoing reconciliation of studies that provide different answers to the same question. Because it is often impractical for readers to track down and review all of the primary studies, review articles are an important source of summarized evidence on a particular topic **(Garg et al., 2008).**

A randomized controlled trial (RCT) is an experimental design in which subjects are randomly assigned to an experimental or control group permitting the strongest inferences about cause and effect. The results of a randomized controlled trial (RCT) provide the strongest evidence of efficacy, that is, whether an intervention is effective when applied to a selective sample under controlled conditions or not **(Campbell et al., 2006).**

The gold standard for testing theory-based interventions' effectiveness is the randomized controlled trial (RCT). The systematic review or meta-analysis of randomized controlled trials (RCTs) is considered to be the strongest evidence **(Cottrell and Mckenzie, 2005).**

According to **Attia and Abdel-Raouf (2007),** Randomized controlled trial (RCT) is considered the gold stander of clinical research. It is the method of choice to compare and study therapeutic interventions and diagnostic tests. It generates the highest level of evidence especially in questions related to intervention and assessment.

It is reported that although the results of a randomized controlled trial (RCT) provide the strongest evidence of cause and effect relationship between the intervention and outcomes, trials are often difficult to implement with children with developmental disabilities **(Campbell et al., 2006).**

Hierarchy of Evidence:

Evidence generated from research is not all the same. Some evidence is better than other. Whenever searching for evidence, one should start looking for the best available one (in descending order of importance) which is obtained from:

- Systematic reviews and meta-analysis.
- Randomized controlled studies.
- Non-randomized controlled studies and cohort studies.
- Case control studies.
- Case series.
- Case reports.
- Opinions of experts or respected authorities.
- Animal research and vitro studies.

Systematic reviews and meta-analysis lie on top of the evidence pyramid both in public health and clinical medicine **(Abdelghaffar, 2007).**

Levels of Evidence for Group designs

I Systematic review of randomized controlled trials (RCT)

Large RCT (with narrow confidence intervals) (n>100)

II Smaller RCT's (with wider confidence intervals) (n<100)

Systematic reviews of cohort studies

"Outcomes research" (very large ecologic studies)

III Cohort studies (must have concurrent group)

Systematic reviews of case control studies

IV Case series

Cohort study without concurrent control group (e.g. with

Historical control group)

Case-control study

V Expert Opinion

Case study or report

Benech research

Expert opinion based on theory or physiologic research Common

Sence/anecdotes **(Abdelghaffar, 2007).**

Wound healing is characterized by the restoration of the epithelial surface. The process of second intention wound healing consists of contraction and epithelialization. These two processes broadly overlap and begin shortly after wound formation. Epithelial cells proliferate, flatten out, and migrate out over the exposed dermal border and adjacent granulation bed, in order to restore the epithelial surface. At the same time, normal skin bordering the defect is pulled towards the center of the wound. This so-called WC phenomenon is caused by the contraction of myofibroblasts, which are attached to the underlying dermis of the bordering skin margin and the panniculus muscle layer **(Milgram et al., 2004).**

The overlapping segments of the repair process are conceptually defined as inflammation, proliferation, and remodeling. During the inflammatory phase, hemostasis occurs and an acute inflammatory infiltrate ensues. The proliferative phase is characterized by fibroplasia, granulation, contraction, and epithelialization. The final phase is remodeling, which is commonly described as scar maturation **(Lorenz and Longaker, 2003).**

The earliest reported use of magnetic therapy to aid wound healing dates to the 1600s, when electrically charged gold leaf was applied to smallpox lesions in an attempt to prevent scarring. Although there is ample experimental and clinical evidence supporting the use of magnetic fields to aid bone healing, its application for soft tissue healing, including skin and tendons, is still ambiguous. Promising research along these lines was first produced in the 1960s by **(Becker, 1961).**

In a study involving limb amputations in frogs, a species that does not naturally produce this current and that is normally incapable of limb regeneration, induction of this current stimulated the regeneration of a rudimentary limb that included cartilage, nerve, and skin tissues **(Borgens et al., 1977 b).** These skin circuits have been identified in humans and are similar in magnitude to those demonstrated in amphibians) Foulds **and Barkr, 1983)**. Given this fact, it is plausible that external magnetic therapy could influence soft tissue healing in humans as well.

Treatments that use electrical stimulation and magnetic fields have long been a topic of controversy and debate. During the last several decades, electromagnetic fields have been used for treatment of nerve regeneration, wound healing, graft healing, diabetes mellitus, myocardial ischemia, and cerebral ischemia. Potential benefits of magnetic field therapies have included osteogenesis for the healing of delayed union and nonunion fractures as well as pseudoarthroses; the control of malignant growths, healing of suppurative wounds associated with diabetes, size reduction of decubital ulcers, and treatment of varicose veins in humans have also been reported. In rat models, results of healing of skin wounds that were exposed to low and extremely low pulsed electromagnetic fields varied. Microbial growth has been inhibited after treatment with alternating low-frequency fields **(Trostel et al., 2003).**

Static and dynamic electromagnetic fields have been studied. Static magnetic fields have a constant electric voltage and include electromagnets with a constant DC charge or fields created by a ferrous magnet. Dynamic magnetic fields are variable energy fields that are continuously changing. They include pulsating electromagnetic fields, low-intensity pulsed ultrasound, sinusoidal electromagnetic fields, and PTEFs like that used in the study reported here. Currently, most of the magnetic fields used for medical therapy and research are dynamic magnetic fields with a changing electrical voltage. Dynamic fields have a greater effect on wound healing in rats than do static fields **(Pienkowski et al., 1994).**

Tissues exposed to PEMF undergo metabolic changes at the cellular level. The exact mechanism by which electromagnetic fields affect bone and other tissues has yet to be elucidated. Several mechanisms have been proposed, among them changes in cellular ionic calcium, modified receptor and messenger behavior, increased synthesis or degradation of substances, and even direct interaction with genes **(Friedenberg et al., 1971).**

In addition to accelerated wound healing, magnetic field (MF) modalities have been shown to significantly increase local blood flow in the stimulated area improving the status of the ischemic tissue. There are in vitro studies suggesting significant alterations in cell division or differentiation which are important for wound healing **(Dunn et al., 1988; Bassett, 1989 and Markov, 1994).**

Magnetic and electric stimulation has been associated with increased collagen deposition, enhanced ion transport, amino acid uptake, fibroblast migration, ATP, and protein synthesis, including a significant increase in the rate of protein and DNA synthesis after stimulation of human fibroblasts in tissue culture **(Luben, 1994; Sisken and Walker, 1995; Rosch and Markov, 2004; Dini and Abbro, 2005 and Okano et al., 2005).**

One area of interest is the effect of EMF and MF on cell proliferation. Most cells normally differentiate to a specific morphology and function. In pathological conditions, cell proliferation is usually suppressed (in conditions of chronic wounds) or enhanced (in the case of neoplastic growth). Magnetic field stimulation of the skin fibroblast resulting in significant increase in collagen secretion and protein concentration has been reported, and these results suggest a favorable alteration in the proliferative and migratory capacity of epithelial and connective tissue cells involved in tissue regeneration and repair **(Bourguignon and Bourguignon, 1989 and Rodeman et al., 1989).**

Two problems related to healing of chronic injuries are tissue ischemia and restoration of normal communication between cells and their environment. Healing requires an optimization of the supply of nutrients and oxygen which allows surrounding tissues to grow and restore physical and chemical functions. An important part of intracellular communication in healing is performed by peptide signaling molecules—growth factors, which enable communication between cells involved in the healing process and between cells and their environment, thus restoring local homeostatic equilibrium **(Nordenstrom, 1983)**.

It has been suggested that at least five components of any vascularized part of the body might participate in EMF initiated bioeffects: (i) blood vessel walls; (ii) intravascular plasma conduction; (iii) insulating tissue matrix; (iv) conducting interstitial fluid; and (v) electrical junctions for redox reactions (transcapillary junctions). The results from treatment of edema indeed suggested that EMF affects sympathetic outflow, inducing vasoconstriction which restricts the movement of blood constituents from vascular to extravascular compartments of the injury site **(Reed, 1988).**

(**Rosenspire et al. 2001 and Rosenspire et al., 2005)** employed a weak EMF to the amplitude of NAD (P)H oscillations to evaluate the effects of the EMF on fibroblasts in an in vitro model of wound healing. Recently, it was demonstrated that a much stronger EMF could accelerate normal and diabetic wound healing by increasing vascular density. The authors demonstrated that the EMF could activate the proliferation of endothelial cells

In the study of **Hou et al. (1999),** it is hypothesized that the main mechanism of non-invasive EMF influence is the induction of electrical currents in cells surrounding the target cells. It is possible that similar effects are induced by the super-week (5nW/cm2) high-frequency EMF employed in fibroblast experiments, where enhancement of natural oscillations in water molecules might enhance super-weak currents in cellular structures.

2. Materials and Methods

Subjects

Search Strategy for Identification of Studies:

Search was done in: Pub Med (Medline), the Cochrane Library and Physiotherapy Evidence Database (Pedro) to systematically review studies published in English language which study the effects of electromagnetic field on wound healing in venous ulcer. The following key words were used in the search. Systematic Review, Electromagnetic Review, Electromagnetic Field, Wound Healing and Venous Ulcers. Reference lists in the relevant studies and review articles were examined.

Methods:

Study Selection Criteria:

Types of Studies:

Randomized control trail of different types of electromagnetic field on wound healing in venous ulcers.

Types of Participants

The review will include Participants with venous ulcers.

Types of Interventions:

This review will include studies which demonstrate the effects of electromagnetic field on wound healing in venous ulcers with reported findings for analysis of its effectiveness.

Exclusion criteria:

- Unpublished studies.
- Studies that compared electromagnetic field on wound healing in venous ulcers with the effects of medications, surgery were excluded.
- Studies that combined electromagnetic field on wound healing in venous ulcers with other types of modalities.
- Non-randomized control trials studies.

Quality assessment of methodology:

All the included studies were scored on their methodological rigor with the Physiotherapy Evidence Database (Pedro) scale **(Pedro, 201 0).** The Pedro scale examines 11 aspects of the quality of methodology. (Table 1)

Data Extraction:

Data from all the included studies were summarized in the following format that included participant's characteristics (Number in each group, target population, diagnosis, numbers in each diagnostic subgroup and each), intervention used, control used, research design and level of evidence for the study, and outcomes of interest.

Data Analysis

Meta-analysis is a quantitative method employing statistical techniques, to combine and summarize the results of studies that address the same question without major differences in its inclusion or exclusion criteria of the participants, mode of administration, doses, and duration of the intervention as well as the comparison intervention, and the outcomes assessed and the methods of their assessment. Studies were clinically, methodologically and statistically homogenous before combining its results. So, Meta-analysis was done to eight studies as they are homogenous and one study excluded as it is heterogeneous.

Table (1) PEDRO scale:

Criteria	No	Yes
1. Eligibility criteria were specified		
2. Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated in the order in which treatments were received)		
3. Allocation was concealed		
4. The groups were similar at baseline regarding the most important prognostic indicators		
5. There was blinding of all subjects		
6. There was blinding of all therapists who administered the therapy		
7. There was blinding of all assessors who measured at least one key outcome		
8. Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups		
9. All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analyzed by "intention to treat"		
10. The results of between-group statistical comparisons are reported for at least one key outcome		
11. The study provides both point measures and measures of variability for at least one key outcome		

3. Results and Discussion

Methodological Quality results:

The scoring of each study with the physiotherapy evidence database (Pedro) scale is listed in Table (2 and 3).

Table (2): Methodology assessment of studies according to the physiotherapy Evidence database (PEDro) scale

Criteria	Abaas S. A et al 2017	Ieran M et al 1990	Stiller M.J et al., 1992
Specified eligibility criteria	YES	YES	YES
Random allocation of participants	YES	YES	YES
Concealed allocation	NO	YES	NO
Similar prognosis at baseline	YES	NO	YES
Blinded participant	YES	YES	NO
Blinded therapists	YES	YES	NO
Blinded assessor	YES	NO	NO
More than 85% follow –up for at least one key outcome	YES	NO	YES
Intention to treat analysis	NO	NO	NO
Between group statistical analysis for at least one key outcome	YES	YES	YES
Point estimates of variability for at least one key outcome	YES	YES	NO
PEDro score	8/10	6/10	5/10

Table (3): Summary of study results

	Abaas S. Aet al 2017	Ieran M et al 1990	Stiller M.J et al., 1992
Intervention	JAMAVA paramagnet therapeutic devices for once daily, three times per week for 2 month for 20 minutes	The stimulator 3-4 h per day for 90 days	Portable device for 3 h daily for 8 weeks
Outcome of interest	Pulsed electromagnetic filed therapy was superior decreasing wound surface area	No significant difference was observed in the healing rateal ulcers	Improved wound healing
Measures	Size of the wound area using wound tracing method	Size of the wound area using wound tracing method	Wound surface area
Component of health	Patients activity and participant	Patients activity and participant	Patients activity and participant

The scores of the all studies included in the study were listed in the table, the more the number of scores of the aspects evaluating the quality of the study, the more the quality of the study.

The three studies show the effectiveness of electromagnetic field on wound healing on venous ulcers **(Abass S. A et al., 2017), (Ieran M et al., 1990) and (Stiller M.J et al., 1992).**

These data collected from the three studies and analyzed statistically using the mean difference resulting in relative effective of the different upper of electromagnetic field on wound healing on venous ulcers.

Low pulsed magnetic field (LPMF) is a very effective biophysical modality used in physical therapy and utilized for acceleration therapeutic purposes as well as in the area of diagnoses.

Electromagnetic field has been shown to influence epidermal cell proliferation and migration and dermal fibroblastic activity (collagen secretion). It is believed that electromagnetic fields play its role in healing by guiding cellular movements that close wounds. It has been shown that fields can affect orientation, migration and proliferation of cells such as fibroblasts, my fibroblasts and keratiocytes, which are of key importance in healing22-23. Initial acceleration of wound healing with a non-invasive method, such as PEMF, may be important in reducing bacteria accumulation stimulating growth factors, cytokine production, and reducing early inflammation, thus creating an appropriate environment to facilitate tissue regeneration. (**Abaas S.A et al., 2017).**

Magnetic and electric field stimulation have been associated with increased collagen deposition, enhanced ionic transport, amino acid uptake, fibroblast migration, and adenosine triphosphate (ATP) proteinsynthesis, including an increased rate of synthesis of protein and DNA 25-26.

Pulsed electromagnetic field found to be effective in wound healing as it enhanced wound epithelization in open cutaneous wounds and provide indications of early contraction without significant short –term changes in other variable.(**Abaas S.A et al., 2017).**

The effect of 4 h of stimulation with PEMF, monitored with the clock inside the unit, is observed both in the case of small ulcers and in the case of large ones. According to the physician's evaluation on the effectiveness of the treatment, 15 patients in the actively stimulated group scored good or excellent vs. 10 in the placebo group the electromagnetic stimulation can influence the repair process at several levels; at the cellular level, it has been shown that fibroblast proliferation and collagen production are increased following PEMF exposure (19,23). In vitro studies have shown that angiogenesis is increased by pulsed electromagnetic fields (1). In vivo in a rat skin wound model, both effects have been reported: very early appearance of newly formed vascular network and collagen formation and maturation **(Stiller M.J et al., 1992).**

The results of this study indicate that PEMF stimulation effectively and safely enhances the healing of recalcitrant venous stasis ulcers. Active PEIAIT therapy, 3 h daily for 8 weeks, led to a 47% decrease in wound area, a significant decrease in wound depth, 1 5% increase in healthy granulation tissue, and improved pain intensity scores. The patients who continued active treatment to 12 weeks exhibited further improvement (66% decrease in wound area). It is also noteworthy that half of the PEMF-stimulated ulcers healed or improved markedly, compared with none in the placebo group.

It is well known that venous leg ulcers may spontaneously improve or worsen**. Ieran *et al.* evaluating** the effect of a unidirectional PEMF device on venous ulcers reported significant spontaneous healing in their control group {30% decrease in wound size over 90 days). PEMF stimulation facilitates ulcer healing by simply accelerating the normal healing process or by altering the mechanism of wound healing cannot be ascertained from this investigation. In a recent review of clinical applications of electric fields in soft tissue repair. Canaday and Lee concluded that electric or magnetic fields may accelerate wound healing only under circumstances in which the healing process is delayed or arrested, i.e. conditions of deficient or absent electrical current."' It is also of interest that to date, no healing enhancing agent has significantly altered the kinetics of normal healing (**Ieran M et al., 1990).**

Stimulation with sinusoidal electromagnetic fields has been shown to induce differentiation of human skin

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Hbroblasts and increase collagen and total protein synthesis."^ PEMF stimulation employing physical parameters similar to those used in the present investigation resulted in enhanced proliferation of fibroblasts. As measured by increased DNA synthesis (N. Guzelsu *et al.* unpublished data). Increased angiogenesis in response to PKMFs is also thought to play a role in wound healing. Yen-Patton *et al.* reported that endothelial cells in culture grow at a higher rate and reorganize into three dimensional vessel-like structures in the presence of a PEMF. The specificity of the electromagnetic stimulus response relationship is clearly demonstrated in the transcription studies by Goodman *et*a. Exposure of human cultured cells (HL 60) to PEMFs with different characteristics resulted in signal-specific quantitative changes in RNA transcripts (**Ieran M et al., 1990).**

The effect of exposure to pulse extremely –low-frequency magnetic field on skin wounds in rats with skin wounds surgically created on their backs was examined. Significant increase in the rate of wound contraction was found in rats treated with magnetic fields. Forty two days after surgery all treated animal showed fully closed wounds. The treated rats showed earlier cellular organization, collagen formation and maturation, and Avery early appearance of newly formed vascular network28. (**Abaas S.A et al., 2017).** The present research study, performed in a double-blind manner, using a homogeneous group of patients undergoing active or dummy stimulation, shows that **4** h of stimulation with PEMF significantly favors the healing of skin ulcers of venous origin. We conclude that stimulation with PEMF **is** useful in obtaining the healing of a very high percentage of ulcers, in a short time. However, healing is only the first step in the treatment of these patients; once it is obtained, the underlying hemodynamic problem must be corrected, if possible, to prevent the otherwise certain recurrence of the ulcer **(Stiller M.J et al., 1992).**

A randomized, double-blinded, placebo-controlled study to evaluate the effect of pulsing electromagnetic fields on the biomechanic strength of rat Achilles' tendons at 3 weeks after transection and repair was applied. The results showed that the animals receiving PMF exposure, showed an increase in tensile strength of up to 69% was noted at the repair site of the rat Achilles' tendon at 3 weeks after transection and repair compared with non-stimulated control animals. So the conclusion was that the application of electromagnetic fields, configured to enhance Ca (2+) binding in the growth factor cascades involved in tissue healing, achieved a marked increase of tensile strength at the repair site in this animal model. If similar effects occur in humans, rehabilitation could begin earlier and the risk of developing adhesions or rupturing the tendon in the early postoperative period could be reduced (**Abaas S.A et al., 2017).**

Conclusion

The current level of evidence to support the effectiveness of electromagnetic filed on wound healing.

In conclusion, the study provides evidence that electromagnetic field can accelerate the healing process of vinous ulcers. The data indicate that the percentage of wound surface reduction in an electromagnetic field group was statistically greater than in a place of group and the meantime of healing was lower, though this difference was not statistically significant.

Therefore, it is necessary to continue such randomized controlled. Studies including larger groups and a longer time of follow-up.

Conflict of interest

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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