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Physical therapy in burn wound healing: Development of clinical prediction rules to identify the efficacy of pulsed electromagnetic therapy

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ABSTRACT

Many studies have demonstrated the effect of pulsed electromagnetic therapy (PEMT) on wound healing. This study aimed to develop a clinical prediction rule (CPR) to assess PEMT's efficacy in burn healing, potentially enhancing treatment decisions and outcomes. It was a one-group intervention study with 46 patients (21 males, 25 females) aged 20 to 55 years, having partial-thickness burns in the first or second healing stage, and a total burned surface area (TBSA) over 15%. The intervention involved pulsed electromagnetic therapy (Fisioline, Italy) for up to six weeks, with 60-minute sessions at 12 Hz and 12 Gauss, three times per week. The statistical analysis was conducted using the SPSS. The study revealed a significant decline in wound surface area (WSA) post-intervention ($p < 0.05$). A significant negative relationship was found between wound improvement and both age and total body surface area (TBSA) ($p < 0.05$), while a significant positive relationship was observed between wound improvement and initial wound size ($p < 0.05$). No significant relationship was found between wound improvement and wound stage ($p > 0.05$). The study concluded that pulsed electromagnetic therapy significantly reduces wound surface area. Additionally, age, TBSA, and initial burn wound size are important predictors of the therapy's efficacy in treating burn wounds.

KEYWORDS

Burn; Wound; Clinical Prediction; Pulsed Electromagnetic Therapy

1. INTRODUCTION

Burns are among the most challenging traumatic experiences an individual can go through, having significant impacts on both the patient and society. Burn wounds are usually caused by various physical and chemical factors, which require different care regimens than those used for other types of wounds. Burn wounds are initially sterile compared to most other wounds. Despite this, the main cause of death in severe burns is wound infection and septicemia, which result from immunodeficiency. Dressing agents and antimicrobial creams used for traumatic wounds are ineffective for deep burns (Press, 1997; Tiwari, 2012).

Although partial-thickness burns can heal spontaneously with slight or no scarring, many physical therapy treatment approaches, such as electrical stimulation (ES), magnetic field therapy (MFT), laser treatment, and ultrasound, are thought to quicken the recovery process and improve scar quality (Sauer & Rudy, 1980; Schlager et al., 2000; Cambier & Vanderstraeten, 1997).

Pulsed electromagnetic field (PEMF) therapy is a non-invasive, non-thermal treatment that includes both electric and magnetic field and is related with a definite amount of electromagnetic (EM) energy. It uses electricity to form series of magnetic pulses through injured tissue whereby each magnetic pulse induces a small electrical signal which induces cellular repair (Benazzo et al., 2008).

Clinical prediction rules (CPRs) are mathematical tools that are commonly used in medical practice. In physical therapy practice, it aids physiotherapists in their daily clinical decision making. They provide physiotherapists with evidence-based resources for aiding patient management by aiding in the diagnosis of specific conditions, recommendation of suitable treatments, or predicting patient outcomes. So, CPRs provide diagnostic, prognostic, or prescriptive functions within the field of physiotherapy. The use of CPRs has witnessed a substantial increase in popularity in recent years (Brennan et al., 2008; Cleland et al., 2007).

According to existing evidence, burn wounds have a profound negative effect on both the individual patient and society (Bishop, 2004). Furthermore, while studies show that pulsed electromagnetic field therapy (PEMT) can be useful in wound healing, there is a lack of comprehensive data and quantitative knowledge in existing research regarding CPRs to identify the efficacy of PEMT in burn wound healing (Kwan et al., 2015; Randolph et al., 1998). Therefore, this study was undertaken to assist physical therapists in predicting which burn patients may benefit from PEMT, thereby improving outcomes, saving time, and reducing healthcare costs. This study aims to develop a clinical prediction rule (CPR) to assess the efficacy of PEMT in burn healing, which could enhance treatment decisions and patient outcomes.

2. METHODS

2.1. Study Design and Participants

This study was a one-group intervention study conducted on forty-six patients (21 males and 25 females) with partial-thickness burn wounds in the first or second wound healing stage, and a total burned surface area (TBSA) of more than 15%. The patients' ages ranged from 20 to 55 years. After recruiting eligible patients, the following were excluded: individuals in the third stage of wound healing, patients with diabetes or undergoing immunosuppressive therapy, and those with comorbidities such as neurological, inflammatory, or infectious diseases.

The burn wounds were classified as stage I (inflammatory) or stage II (proliferative) based on the stage of healing, clinical features, and wound duration. The TBSA was measured using the Rule of Nine method. The study was conducted in the in-patient burn unit of AHMED ORABI Hospital, Egypt, from December 2022 to May 2023.

Procedures were explained to all patients and informed consent was completed prior to group allocation. This research was approved by The Ethical and Research Committee of Faculty of physical therapy, Cairo University, Egypt (P.T.REC/012/003534) and registered at ClinicalTrials.gov (NCT05341427) prospectively.

2.2. Outcome Measures

The wound surface area (WSA) was measured before (baseline) and after six weeks of intervention. A disposable transparent grid paper was placed on top of the wound, which had been cleaned with alcohol before use. The margin of the wound was then traced using a fine pen marker, with the area measured in cm^2. A metric graph sheet was used to measure the WSA by counting the filled squares within the wound's border and regrouping the partially filled squares. To ensure the reliability of the measurements, each wound was traced three times. The final measure used for analysis was determined by averaging the values obtained from these three tracings (Spinczyk & Wideł, 2017).

2.3. Interventions

The intervention program included the use of PEMF therapy (Fisioline, made in Italy) for up to six weeks in addition to routine wound care. The forty-six patients in our intervention group received 60 minutes of local application of PEMF therapy, with a frequency of 12 Hz and an intensity of 12 Gauss, three times per week for six weeks on the wound area.

2.4. Clinical Prediction Methodology

Four variables were used to predict the efficacy of PEMF therapy.

Method of Variable Selection: Beyond sampling, another methodological consideration was deriving a prediction rule from a small number of potential predictor variables. It was important to include all potential predictor variables that could influence the derived rule. Variables were drawn from history, physical examination, self-report measures, and diagnostic tests. For this reason, many initial predictor sets were based on prior studies. According to this approach, our CPR study used four variables (age, TBSA, initial wound size, and stage of burn) to predict the efficacy of electromagnetic therapy on burn wounds.

2.5. Sample Size Calculation

The sample size was calculated according to the researcher’s opinions who have suggested that at least 10- 15 patients per potential predictor variable be included in the studies of physical therapy research (Concato et al., 1993).

2.6. Statistical Analysis

The statistical analysis was conducted using the SPSS Package program version 25 for Windows (SPSS, Inc., Chicago, IL). Descriptive statistics for quantitative data included the mean and standard deviation for age, total body surface area (TBSA), and wound surface area (WSA). The qualitative stage variable data were expressed as numbers and percentages. Pearson’s correlation coefficient was used to compute the relation and direction between age, TBSA, and initial wound size with the mean differences of WSA. Spearman's correlation coefficient was used to assess the relation and direction of the stage with the mean differences of WSA. A p-value of ≤ 0.05 was considered statistically significant.

3. RESULTS

A total of 61 patients were assessed for eligibility, of whom 55 participated in the trial, and follow-up data were obtained from 46 patients. The study consort diagram is shown in Figure 1. No side effects attributable to the intervention were recorded.

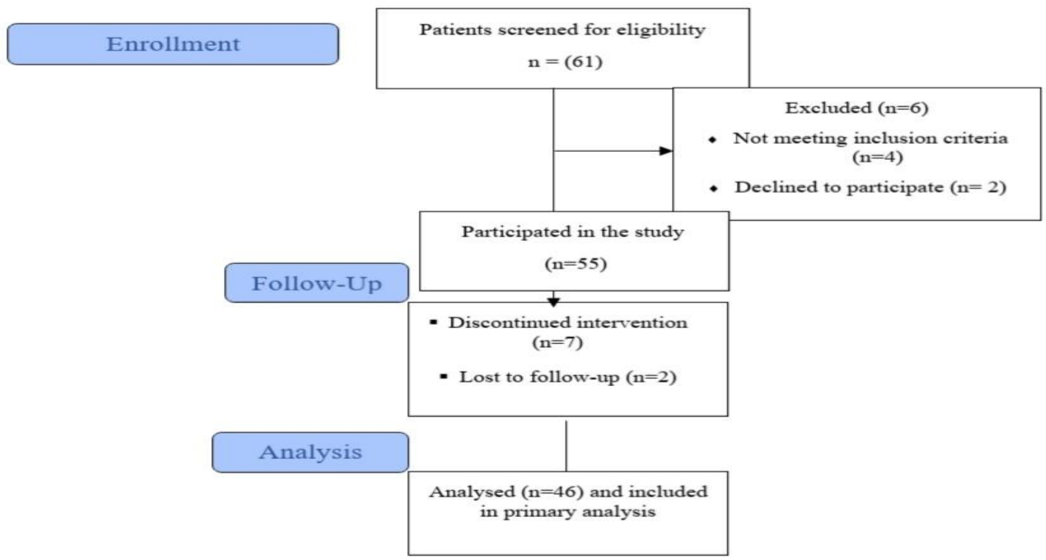

Figure 1. Consort diagram for the study

In the current study, the mean ± SD values for age, TBSA, and initial wound size at pre-WSA were 36.07 ± 8.90, 29.74 ± 6.60, and 24.38 ± 3.52, respectively, for the patients (Table 1). The distribution of stages I and II was 37 (46.3%) and 32 (40.0%), respectively (Table 1).

Table 1. Demographic and clinical characteristic of the patients

Variables	Participants		
	Mean ±SD[1]	**Minimum**	**Maximum**
Age (year)	36.07±8.90	21	50
TBSA	29.74±6.602	15	42
Initial wound size (Pre-WSA)	24.3789±3.52	12.60	34.10
	Percentage[2]	Minimum	Maximum
Stages (Stage I: Stage II)	37 (46.3%), and 32 (40.0%)	1	3

Note: Data are expressed as mean ±standard deviation for age, TBSA, and initial wound size; Data are expressed as number (percentage) for stages.

Before and after intervention comparison of WSA, there was a statistically significant decline in the wound surface area ($p < 0.05$) in post-intervention values when compared to the baseline values (Table 2).

Table 2. Comparison of Wound Surface Area (WSA) Before and After Intervention

Variables	Mean ±SD (n=80)	Mean difference (Improvement)	Total wounding improvement
Pre-WSA	24.3789±3.52	10.95	48525.961±979.598
Post-WSA	13.42±2.71		

Note: Data are expressed as mean ± standard deviation; p-value: probability value; Significant: p < 0.05.

In Table 3, we examined the relationships between total wound improvement and several key variables: age, TBSA, Pre-WSA, and stage. Age exhibited a highly significant negative correlation with total wound improvement, as indicated by a substantial correlation coefficient of 0.430 ($p < 0.001$). This suggests that, as age increases, total wound improvement tends to decrease as well, highlighting the potential role of age as a predictor of negative wound healing outcomes. TBSA showed a weak negative correlation ($r = 0.128$, $p < 0.001$) with total wound improvement. While statistically significant, the relationship between TBSA and wound improvement is not as strong as age, implying that the extent of the body's surface area affected by the wound has a comparatively smaller impact on wound healing outcomes.

Pre-WSA exhibited the most robust positive correlation, with a correlation coefficient of 0.671 ($p < 0.001$). This suggests that a larger initial wound size is significantly associated with greater total wound improvement, emphasizing the importance of considering the size of the wound at the outset of treatment. On the other hand, the Stage variable displayed a weak negative correlation with total wound improvement, with a correlation coefficient of -0.089. However, this correlation was not statistically significant ($p = 0.43$), indicating that there is no conclusive evidence of a relationship between the stage of the wound and the extent of total wound improvement (Table 3).

In summary, this analysis reveals that age, Pre-WSA, and to a lesser extent, TBSA, are important factors associated with total wound improvement. These findings may have practical implications for clinicians and researchers working on wound management and suggest that interventions should consider patient age and initial wound size as potential determinants of successful wound healing outcomes.

Table 3. Relationship between total wound improvement and age, TBSA, stage, and initial wound size

Variables	Correlation coefficient (r)	*P*-value
Age	-.430**	.000
TBSA	-.128	.000
Pre-WSA	.671**	.000
Stage	-.089	.431

Note: Data are expressed as mean ± standard deviation; r: Pearson's correlation coefficient; p-value: probability value; Significant: p < 0.05

Bi-variate Pearson's correlation coefficients were computed between the mean differences in WSA and age, TBSA, initial wound size, and stage (Table 4). The results revealed a significant negative correlation between both age and TBSA with the mean differences in WSA, and a significant positive correlation between initial wound size and the mean differences in WSA ($p < 0.05$). This indicates that changes in the mean differences in WSA are consistent with changes in age, TBSA, and initial wound size. However, there were no significant correlations between stage and the mean differences in WSA ($p > 0.05$), suggesting that changes in the mean differences in WSA are not consistent with changes in stage.

Table 4. Relationship between age, TBSA, initial wound size, stage, and mean differences in WSA

Variables	Correlation coefficient (r)	*P*-value
Age	-.181	0.0001*
TBSA	-.062	0.0001*
Pre-WSA	.646**	.000
Wound stage	.220*	.050

Note: Data are expressed as mean ± standard deviation; r: Pearson's correlation coefficient; p-value: probability value; Significant: p < 0.05

In Table 5, we investigated the predictive findings regarding the association between key variables (age, TBSA, pre-wound surface area or pre-WSA, and stage) and their impact on mean differences in wound surface area (WSA), using both univariate and multivariate regression models. In the univariate regression model, age exhibited a significant negative association with WSA, with a β coefficient of -0.35 (95% CI: -0.49 to -0.21) and a p-value of 0.0001. This indicates that as age increases, there is a statistically significant decrease in WSA, suggesting that older individuals tend to experience reduced WSA. TBSA also displayed a significant negative association with WSA in the univariate model, with a β coefficient of -0.48 (95% CI: -0.67 to -0.28) and a p-value of 0.0001. This implies that an increase in the Total Body Surface Area affected by the wound is associated with a decrease in WSA, emphasizing the importance of a larger affected surface area in wound healing.

Pre-WSA had a strong positive association with WSA in the univariate model, with a β coefficient of 0.81 (95% CI: 0.75 to 0.86) and a p-value of 0.0001. This result underscores that a larger initial wound size is positively correlated with greater WSA, indicating that individuals with larger initial wounds tend to exhibit more significant wound surface area improvement. Stage, however, did not show a significant association with WSA in the univariate model, with a non-significant β coefficient of -0.74 (95% CI: -2.88 to 1.42) and a p-value of 0.498.

Moving on to the multivariate regression model, age remained negatively associated with WSA, but its significance was reduced (β = -0.05, p = 0.077). TBSA continued to have a negative association with WSA (β = -0.12, p = 0.001), emphasizing the importance of a larger initial wound size. Pre-WSA also retained its strong positive association with WSA in the multivariate model (β = 0.74, p = 0.0001), indicating its robust predictive value. Interestingly, in the multivariate model, Stage became positively associated with WSA, with a β coefficient of 0.21 and a p-value of 0.501. However, the significance of this association remained non-significant.

In conclusion, the multivariate regression model revealed that Age, TBSA, and Pre-WSA continue to be significant predictors of WSA. While Stage did not exhibit a significant association in either the univariate or multivariate models, the results suggest that Age, initial wound size (Pre-WSA), and the extent of the body's surface area affected by the wound (TBSA) are critical factors to consider when predicting mean differences in WSA. These findings provide valuable insights for healthcare practitioners and researchers in the field of wound management and healing.

Table 5. Predictive findings and their associations with mean differences in WSA in univariate and multivariate regression models

Predictive findings	Univariate regression model		Multivariate regression model	
	β (95% CI)	P-value	β (95% CI)	P-value
Age	-0.35 (-0.49– 0.21)	0.0001*	-0.05 (-0.10– 0.01)	0.077
TBSA	-0.48 (-0.67– 0.28)	0.0001*	-0.12 (-0.19– -0.05)	0.001*
Pre-WSA	0.81 (0.75– 0.86)	0.0001*	0.74 (0.68 – 0.81)	0.0001*
Stage	-0.74 (-2.88– 1.42)	0.498	0.21 (-0.42 – 0.84)	0.501

Note: p-value: probability value; Significant: $p < 0.05$

4. DISCUSSION

The results of our study showed a statistically significant decline in wound surface area (WSA) after the intervention compared to baseline values ($p < 0.05$). Furthermore, a statistically significant negative relationship ($p<0.05$) was found between wound improvement and both age and total body surface area (TBSA). Notably, there are no existing studies that demonstrate a relationship between age and the efficacy of PEMF therapy. Additionally, a statistically significant positive relationship ($p<0.05$) was observed between wound improvement and initial wound size, however, no significant relationship was found between wound improvement and wound stage ($p>0.05$). The improvement in wound healing occurred similarly in both stages, with no significant difference between them.

Physical therapists play a vital role in the comprehensive wound care team. They are not only equipped to administer the traditional wound treatment but also to utilize diverse biophysical methods, encompassing electromagnetic, acoustic, and mechanical approaches, to enhance the healing process. Moreover, physical therapists concentrate on the restoration of function, which is often compromised in patients with both chronic and acute wounds. Considering the numerous physical therapy options for wound care at our disposal, it is of utmost importance to carefully choose the right one to improve wound healing in terms of cost and time efficacy and decrease the societal burden (Zhou et al., 2015).

PEMT has been used clinically to improve healing of chronic ulcers, accelerate wound closure, reduce pain, promote granulation and circulation. PEMT enhances the release of insulin-like growth factor (IGF) and transforming growth factor-beta (TGF-β) by stimulating the capillary vessels formation and the formation of endothelial cell. This process accelerates healing and plays a crucial role in all stages of the healing process. Additionally, it has been observed that it stimulates lysosomes, ribosomes, and mitochondria, thus increasing enzymatic activity. Furthermore, it elevates partial oxygen pressure and aids in getting rid of toxins from the tissue. PEMF therapy involves the activation of the neuromuscular system through low-voltage electric currents and possesses bio-stimulating properties that acts as an infection inhibitor, provides pain relief, activates the immune system, enhances lymph circulation, and regulates blood circulation and metabolism by promoting the formation of new blood vessels (Tabakan et al., 2022; Keskin et al., 2019; Cheing et al., 2014).

Several factors can influence the response of a wound to different physical therapy treatment approaches. These factors include characteristics related to the wound itself (such as type, size, location, chronicity, and infection), the patient's characteristics (such as age, coexisting medical conditions, and individual variability), and the treatment parameters and duration (Guo & Dipietro, 2010).

CPRs are tools created to enhance clinical decision making by statistically integrating clinical findings to improve the accuracy of diagnosis, prognosis, or prediction of response to treatment for individual patients. In physical therapy field, many CPR-related studies have focused on prediction of treatment response. There is an increasing attention to the mechanical aspects of constructing a methodologically sound CPR (Julie and Fritz, 2009). Regarding the effect of PEMF on burn wound healing, the results of this study are consistent with the literature, which supports the use of PEMF in clinical practice (Gualdi et al., 2021; Athanasiou et al., 2007).

This study has developed a Level IV clinical prediction rule (CPR), which should not be immediately considered the definitive CPR for guiding clinical practice. Further research is crucial to determine whether this increase is clinically meaningful. Achieving 100% accuracy in identifying patients is unlikely to be sustained in future studies (McGinn et al., 2000).

5. CONCLUSIONS

This preliminary offers the capacity to proactively pinpoint a specific group of burn wound patients who are likely to experience advantages from PEMF therapy, thereby potentially enhancing clinical decision-making. Results of this study represent the initial stage in the crafting of a predictive guideline Subsequent research endeavors will be required to validate the guideline's accuracy and assess its influence on clinical practices, patient outcomes, and financial considerations. The current investigation reveals a strong correlation between wound surface area improvement and factors like age, total body surface area (TBSA), and the initial wound size. Notably, the efficacy of these factors remains consistent throughout the various stages of burn wound healing.

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CONFLICTS OF INTEREST

The authors declare no conflict of interest.

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