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A STUDY TO DETECT THE EFFICACY OF MICRO-CURRENT THERAPY ON PESSURE ULCERS

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Abstract: Pressure ulcers (PU) are common international afflictions that occur in many different healthcare settings. The aim of this prospective, randomized, multi-center study was to determine the effectiveness of micro-current (MCT) therapy on patients with four chronic stages under The National Pressure Ulcer Advisory Panel (NPUAP). PU on 60 male and female patients enrolled from 6 hospitals. The analysis reveals that MCT has a significant effect on wound healing. Data analysis also reveals that wounds of female patients are healed significantly faster than those of male patients and that age significantly influenced wound healing.

Keywords: Pressure ulcer, micro-current therapy (MCT), hospital, wound healing, multiple regression.

Introduction

Pressure ulcers (PU) are a common dermal, sub dermal affliction caused by compromised patient mobility in many different healthcare settings. Dutch studies have reported that the prevalence of PUs is high, especially in the intensive care unit [1]. The appearance of PUs can range from a very mild pink coloration of the skin, which disappears in a few hours after pressure is relieved on the area, to a very deep wound extending to fascia or sometimes to bone. There has been a trend in modern health care toward minimally invasive procedures, including reduced reliance on heroic and long term drug therapies. A successful, non-invasive intervention reported in numerous studies for managing PUs has utilized milli-amperage and micro-amperage levels of electrical stimulation [2]. Living soft tissues possess measurable DC electric fields that play a role in regulating the healing process. Micro-current therapy involves the exogenous application of low intensity electric currents to the wound to accelerate the rate of healing. Micro-currents are electric currents that have amplitude of less than one milliampere (10^{-6} ampere). In view of available scientific evidence, one would expect a beneficial outcome from electro-therapy that increases the rate of PU healing and results in faster wound closure [3]. One can follow the rate of pressure ulcer by measuring the size of the wound at regular intervals. Numerous clinical studies have reported the acceleration of healing of chronic wounds with the delivery of micro amperage and milliamperage levels of current to the wound. However, the evidence that micro-current therapy predictably accelerates repair of pus requires additional substantiation from clinical research [4].

A statistical analysis of data and results from this prospective study was undertaken with the aim to detect the efficacy of MCT on PUs of patients hospitalized for extended periods of time.

Materials and Methods

Data were collected from PUs of 60 male and female patients between 60 and 80 years of age who were hospitalized. Patients were selected from 6 hospitals in Belgium and were randomized into two groups to avoid investigator bias. Randomisation not only avoided investigator bias

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but also ensured that the two groups were comparable. Treatments were randomly allocated to the group of patients using Simple Random Sampling without replacement in case of each hospital. Simple random Sampling is that kind of randomization method where any group of patients can receive any treatment and any patient can enter any group as well. The patients from one group received MCT while those in the control group (CON group) received visually the same therapy but with an inactive MCT device. All patients were followed for 12 weeks and the surface areas of the wounds were measured on a weekly basis. Some patients were suffering by more than one wound.

Table 1 below shows the variables for which the data were collected. It also shows the names given to these variables in the dataset, and provides information on their units of measure.

Study protocol

Micro current Therapy uses extremely small amounts of electrical current (millionths of an amp) to help relieve pain and heal soft tissues of the body. Injury to the body disrupts its normal electrical activity. Micro current Therapy produces electrical signals like those naturally occurring when the body is repairing damaged tissues. By applying similar electrical currents, the healing process is enhanced. The electrical current used in Micro current Therapy is so small that it is rarely felt. However, the water-moistened electrodes or gel used to conduct the current may seem cool when first applied. We measured the surface area of wound applying the micro currents ranging from 4 miliamperes to 1 femtoampere, or an alternating current with a frequency in the range of 0.00065 Hz to 0.00085 Hz, utilizing large surface area electrodes to achieve to low current densities of less than 5 microamperes per square inch up to 40 minutes at each wound. Other different types of therapy are Maggot therapy, Magnetic therapy, Gene therapy and healing of Specialized Tissues etc.

Our dataset contained 114 wounds. The measurement of surface area for each wound was taken for 12 consecutive weeks. The measure-

Table 1

Controlled variables, description, type and units of measure.

Variable	Description	Levels/Units of measure
Treatment	Treatment group to which the patient was assigned	CON=0, MET=1
Sex	Patient’s sex (gender)	0=male, 1=female
Age	Patient’s age	Years
Hospital	Hospital at which the patient was enrolled	1, 2, …, 6
Wounds identified	Number of wounds on each patient	1, 2, 3
Weeks	Weeks of wound measurement	0, 1,…, 12
Baseline	The surface area of the wound at week 0, just before treatment commenced	Square millimetres
Surface areas	The surface area or the wound per week, from week 1 to week 12.	Square millimetres

ments of a wound as shown below were Y_0, Y_1, Y_2,...,Y_{12} where, Y_0 is the base measurement of the wound and t = 0,1,2,...,12 weeks. Assuming that the surface area of the wound at time t is a function of the surface at time t –1, we derived the rate of change in surface area of a wound for the 12 weeks as follows.

Assuming $Y_t = CY_{t-1}$ implied that $Y_1 = CY_0$, $Y_2 = CY_1$, $Y_3 = CY_2$, . . ., $Y_{12} = CY_{11}$

where, C was an unknown constant. Using mathematical equations, we came up with an equation that tracked the correlation between all 13 measurements.

$Y_1 = CY_0$, $Y_2 = C^2Y_0$, ..., $Y_{12} = C^{12}Y_0$

In general,

$$Y_t = C^tY_0 \qquad \text{(Eq 1)}$$

To solve for C, which was our main interest, we applied logarithms on equation 1

$\ln C$

$$\text{In } (Y_t) = \text{In}(Y_0) + t(\text{In } C) \qquad \text{(Eq 2)}$$

$$\text{Using } Z_t = \ln(Y_t)\text{-}\ln(Y_0) \qquad \text{(Eq 3)}$$

and combining equations 2 and 3, we obtained

$$Z_t = (\text{In } C)*t \qquad \text{(Eq 4)}$$

Equation 4 can be interpreted as a linear regression model without intercept, i.e. $Z_t = (\text{In } C)*t + \varepsilon$. There was no change in surface area of a wound at week 0. We regressed Z_t on t for each wound. The parameter estimate, $\widehat{\beta}$, from the regression model is equivalent to , i.e. ln

$$C = \widehat{\beta} \Rightarrow C = \exp\left(\hat{\beta}\right)$$

Our response variable C was the rate of change in surface area of a wound, where

C=1 corresponds to no change in the surface area

C<1 corresponds to improvement; the surface area was reducing

C>1 corresponds to deterioration; the surface area was increasing

Regression Model—determination of treatment effect

To examine the treatment effect, multiple linear regression models were used. Cohen and Hardy proposed that any combination of categorical and continuous variables can be analyzed [5] within a multiple regression model framework simply through the dummy coding of the categorical variables. In this study, we chose to assess the treatment effect using the multiple linear regression models of Kutner *et al.* [6]. Therefore, in our study:

$$Y = \beta_0 + \beta_1 X_1 + \beta_2 X_2 + \beta_3 X_3 + \beta_4 X_4 + \beta_5 X_5 + \beta_6 X_6 + \beta_7 X_7 + \beta_8 X_8 + \varepsilon;\ \varepsilon \sim N(0,\sigma^2)$$

where,

Y = Rate of change in wound surface area (C)
X_1 = Treatment
X_2 = Sex
X_3 = Age
X_4, X_5, X_6, X_7, X_8 = Hospital (H) 1, H2, H3, H4 and H5 respectively.

Since the variable Hospital is a categorical variable, we thus created dummy variables considering Hospital 6 as a reference hospital.

$$X_1 = \begin{cases} 1 \text{ if a wound belong to the MET group} \\ 0 \text{ otherwise} \end{cases}$$

$$X_2 = \begin{cases} 1 \text{ if a patient gender is Female} \\ 0 \text{ otherwise} \end{cases}$$

$$X_4 = \begin{cases} 1 \text{ if patient is in hospital 1} \\ 0 \text{ otherwise} \end{cases},$$

$$X_5 = \begin{cases} 1 \text{ if patient is in hospital 2} \\ 0 \text{ otherwise} \end{cases},$$

$$X_6 = \begin{cases} 1 \text{ if patient is in hospital 3} \\ 0 \text{ otherwise} \end{cases},$$

$$X_7 = \begin{cases} 1 \text{ if patient is in hospital 4} \\ 0 \text{ otherwise} \end{cases},$$

$$X_8 = \begin{cases} 1 \text{ if patient is in hospital 5} \\ 0 \text{ otherwise} \end{cases}$$

Results

Overall, healing rate ranged from 0.7340 to 1.0838, with a mean of 0.9240 and standard deviation 0.0807. In the CON group, the healing rate ranged from 0.8551 to 1.0838, with mean 0.9455 and standard deviation 0.076. In the MCT group, the healing rate ranged from 0.7340 to 1.0511 with a mean of 0.9455 and standard deviation of 0.0760 (Table 2).

Overall, the age ranged from 60 to 79 years in the CON group, with mean 69.33 and standard deviation 6.23. In the CON group, age ranged from 60 to 79 years, with mean 69.6 and standard deviation 5.93. In the MCT group, age ranged from 61 to 78 with a mean of 69.07 and standard deviation of 6.72 (Table 2).

Table 2
Statistics for wound surface area rate of change and age.

Variable	Group	n	Mean	Standard Deviation	Minimum	Maximum
Rate of change in surface area of wound (mm^2/week)	Control	60	0.9455	0.0760	0.8551	1.0838
	MCT	54	0.9002	0.0803	0.7340	1.0511
	Total	114	0.9240	0.0807	0.7340	1.0838
Age (in years)	Control	30	69.60	5.93	60	79
	MCT	30	69.07	6.72	61	78
	Total	60	69.33	6.23	60	79

Table 3
Frequency distributions of gender in the Control and MCT groups.

Sex	CON		MCT		Total	
	frequency	Percent	frequency	Percent	Total	Percent
Female	14	23.33	32	59.30	46	40.35
Male	46	76.67	22	40.70	68	59.65
Total	60	52.63	54	47.37	114	100.00

Table 4
Average pre-study surface area (mm^2) dimensions for each stage for both males and females.

Sex	Number of patients	Number of wounds	Stages			
			I	II	III	IV
Male	46	89	130.85	141.35	160.24	180.52
Female	14	35	191.12	210.78	299.59	361.41

In general, 40.35% of wounds were from female and 59.65% from male patients. In the CON group the distribution of wounds by gender was about 23.33% from male and 76.76% from female, while in the MCT group it was about 59.30% from male and 40.70% from female patients (Table 3).

Overall, the gender distribution was 53% males and 47% females. In the CON group the distribution of gender was 23% females and 77% males, while in the MCT group it was 59% females and 41% males (Table 3). We observed that at each stage female's average pre-study surface area of wound was less than that of male at each stage under the National Pressure Ulcer Advisory Panel (NPUAP) the average pre-study surface area of wound was the highest at stage IV (full thickness tissue loss with exposed bone, tendon muscle) followed by stage III (full thickness tissue loss) for both males and females (Table 4).

Overall, Hospital 2 had the most wounds (33%). Most of the wounds in the CON group were at hospital 2 (43%), while most of the wounds in the MCT group were at hospital 6 (30%) (Table 5). About two-thirds (67%) of the patients had more than one wound on their bodies (Table 6).

Figure 1 shows a trend plot of weekly average surface-base ratios for the control and MCT groups. It can be seen that the surface-base ratio decreased in both groups, but it decreased at a faster rate in the MCT group, suggesting that healing rate in this group was better than in the control group.

Table 5

Frequency distributions by gender and hospital in the Control and the MCT groups.

Hospital	CON		MCT		Total	
	frequency	Percent	frequency	Percent	Total	Percent
1	2	3.33	8	14.81	10	8.77
2	26	43.33	12	22.22	38	33.33
3	12	20.00	8	14.81	20	17.54
4	4	6.67	6	11.11	10	8.77
5	4	6.67	4	7.41	8	7.02
6	12	20	16	29.63	28	24.56
Total	60	52.63	54	47.37	114	100

Table 6

Frequency of wounds per patient.

Number of wounds per patient	Frequency	Percentage
1	22	36.67
2	22	36.67
3	16	26.66
Total	60	100.00

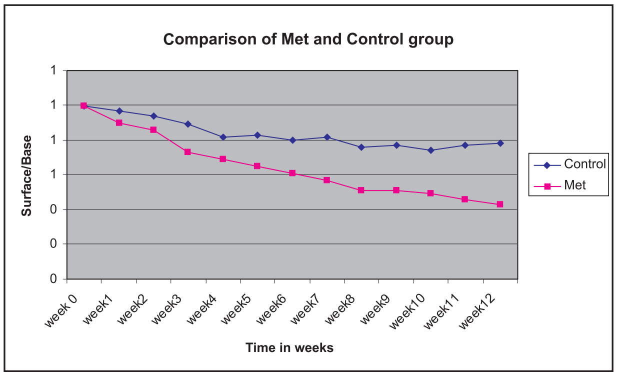

Figure 1
Weekly surface-base ratio for the control and MET groups.

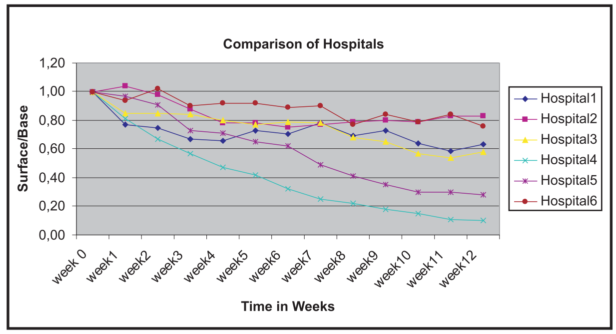

Figure 2
Comparison of weekly surface base ratios at the hospitals.

Figure 2 shows the trend plots average surface base-ratio at the hospitals. The wounds for patients in hospital 4 and 5 decreased in surface-base ratio faster than at other hospitals. There was not much difference in the surface change of wounds for patients in Hospitals 1, 2, 3 and 6. This may suggest that the research protocol was carried out more consistently in hospitals 4 and 5 than in the other hospitals.

Table 7
Cross-tabulation of different variables.

Variable	Asymptotic Significant
Treatment versus Gender Hospital	 * $\chi^2_{(1)}$:15.24 ** $\chi^2_{(5)}$:10.24
Gender versus Hospital	* $\chi^2_{(5)}$:20.00

* 2<0.01, ** 2<0.10

From Table 7, it is seen that the treatments were significantly related to gender and slightly related with hospitals. Gender and hospitals were also significantly associated with each other.

Table 8.
Multiple linear regression analysis of rate of change in surface area of wound.

Variables	Coefficient	SE	t	Sig
(Constant)	0.813	0.088	9.237	0.000
Treatment	-0.031	0.013	-2.505	0.014
Sex	-0.049	0.013	-3.669	0.000
Age	0.003	0.001	2.116	0.037
Hospital 1	0.007	0.025	0.290	0.772
Hospital 2	-0.046	0.017	-2.675	0.009
Hospital 3	-0.062	0.018	-3.352	0.001
Hospital 4	-0.171	0.026	-6.504	0.000
Hospital 5	-0.096	0.026	-3.650	0.000

R^2=0.462

From the Table 8, we observed that the variables Treatment, Sex and Age were significant at 5% level of significance. We also observed that among hospitals all the hospitals were significant at 5% level of significance except Hospital 1.

Discussion

Chronic wounds, of which leg ulcerations make up a major share, are a therapeutic problem. It is estimated that 90% of leg ulcers are due to venous insufficiency, affecting 0.6 of men and 2.1% of women in their 60s [7,8]. In our study, the average rate of change in surface area of wound reduced approximately 5% more in female patients than in male patients, keeping other variables constant (Table 8). Occlusive dressings accelerate wound healing. These probably achieve their effects by promoting a moist environment which resurfaces 40% faster than air-exposed wounds [9,10].

We observed (Table 8) that the overall model is highly significant. The model explained approximately 46% of the total variation by the regressors. Individually every variable has significant effect on healing rate except Hospital 1. Here we also see that average rate of change in surface area of the wound decreases approximately 3% more using MCT than in the control when all other variables were held constant, i.e. significantly contributes to reduction in the rate of change in the surface area of the wound.. Similarly among hospitals, the average rate of change in the surface area of wound decreases more (by 17%) in those patients who were hospitalized in hospital 4 than in those patients who were hospitalized in hospital 6, keeping other variables constant.

Finally, the present study suggests that efficacy of MCT is significant in reducing the rate of change in the surface area of the wound, and the female patients cured better than the male patients. The analysis shows that the hospital factor also influences by reducing the surface area of the wound while age significantly but only slightly decreases wound healing.

In this study there are two weaknesses. One is that the study was conducted considering the wounds to be independent. However, some patients had more than one wound. So, in such cases the wounds could not be considered independent, they were correlated. Another weakness was that the time effect was completely ignored in this study. Considering the time effect, additional clinical research may be needed to support the use of MCT in clinical practice.

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