

Comparative study with multifunctional membranes and wet to dry dressing, in patients with chronic difficult to heal wounds

Randomized clinical trial.

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SUMMARY

Introduction:

Known difficulty in treating chronic wounds from healing, we intend to evaluate differences in the healing progress after intervention with advanced methods (Membranes Multifunctionals) and traditional methods (dressings wet gauze to dry), for a period of study 12 weeks.

Patients and Methods:

A total of 380 patients who presented to the outpatient clinic Healings Department of Surgery Roosevelt Hospital with chronic wounds difficult to heal, They were distributed for treatment in outpatient setting to one of two groups: a. with advanced methods (Membranes Multifunctionals) and b. with traditional methods (wet gauze dressings dry).

Distribution in each group was performed by simple randomization according presentation sequence: odd cases for advanced treatments Membranes Multifunctionals and even cases: traditional cure (wet to dry dressings).

The main outcome of interest was to determine the efficacy relative to the formation of granulation tissue and / or epithelial tissue in the wound bed with the two methods of treatment using for evaluation modified scale Houghton et al (Photographic Wound Assessment Tool-PWAT for its acronym in English)

results:

January to October 2014, 380 eligible patients were selected and randomized 190 patients in each group.

129 patients (92 in the group of wet to dry dressing and 37 Membrane Multifunctional) not completed the study for noncompliance / drop protocol, remaining in the study 251 patients for monitoring.

The time set for data collection was at weeks 4, 8 and 12.

At four weeks, in the first assessment, the treated group showed Membrane Multifunctional complete or near the end healing in 50% of cases, compared with 28% of the wet to dry dressings.

At eight weeks, in the second evaluation, the treated group showed Membrane Multifunctional complete or near the end healing in 71% of cases, compared with 50% of wet to dry dressings.

In the final evaluation at twelve weeks, the treated group showed Membrane Multifunctional complete or near the end healing in 85% of cases, compared with 58% of the wet to dry dressings.

conclusions:

In the present study, chronic wounds in difficult to cure, the treated group was multifunctional membranes alternative offered the most successful full wound closure compared with those treated with wet to dry dressing lesions.

Keywords: Wound healing, advanced treatment, skin ulcers, pressure ulcers, leg ulcers, diabetic foot ulcers, chronic ulcers difficult to heal.

ABSTRACT

Introduction:

Derived from the recognition of the difficulty for the treatment of chronic or hard-to-heal wounds, We Have Proposed to Evaluate the Differences of the progress of the healing after intervention With advanced methods (Multifunctional Membranes) and traditional methods (Wet to dry gauze dressings), During a period of study of 12 weeks.

Patients and Methods:

A Total of 380 Patients presented to WHO Outpatient Wound Care Clinic at Roosevelt Hospital Departments of Surgery, with chronic or hard-to-heal wounds, Were distributed for treatment in outpatient setting to one of two groups: a. With advanced methods (Multifunctional Membranes) and b. With traditional methods (wet-to-dry gauze dressings).

The distribution in each group was made by Simple Randomization ACCORDING TO the presentation sequence: odd cases, treatments for advanced With Multifunctional Membranes and even cases: with traditional cures (wet to dry dressings).

The main outcome of interest was to determine the efficacy in relation to the formation of granulation tissue and / or epithelial tissue in the wound bed with the two treatment methods, using ITS evaluation for the modified scale of Houghton et al. (Photographic Wound Assessment Tool-PWAT for ITS acronym in English-)

results:

From January to October 2014, 380 eligible Patients Were selected, and 190 Patients in each group Were randomized.

129 Patients (92 from the wet-to-dry gauze dressing group and 37 from the Multifunctional Membrane) did not complete the trial due to noncompliance / dropout of the protocol, leaving 251 Patients for follow-up and analysis.

For the information confirmed by the Principal Investigator, the abandonment of the treatment was due to the patient's lack of compliance, due to the frequent painful and traumatic changes in the group of dressings from wet to dry gauze and for other causes in the group of Multifunctional membranes.

The time for data collection was established in weeks 4, 8 and 12.

At the first evaluation at four weeks, the group Treated With the Multifunctional Membrane ADH or almost closed completely healed in 50% of cases, 28% of Compared With wet to dry gauze dressings.

In the second evaluation at eight weeks, the group Treated With The Multifunctional Membrane completely healed or almost closed in 71% of cases, 50% of Compared With wet to dry gauze dressings.

In the evaluation at the end twelve weeks, the group Treated With The Multifunctional Membrane ADH or almost completely healed in 85% of closed cases, Compared With 58% of wet to dry gauze dressings.

conclusions:

In the present study of chronic or hard-to-heal wounds, The group Treated With the multifunctional membranes That was the alternative Offered the greatest success of complete closure of the wound Compared With the lesions Treated With wet-to-dry dressing.

Keywords: Wound healing, advanced treatment, skin ulcer, pressure ulcers, leg ulcers, diabetic foot ulcers, chronic ulcers hard-to-heal.

INTRODUCTION

Conceptual definition

Traditional healing: Healing with daily replacement using traditional cures with saline gauze and the wet method to dry.

Advanced Healing: Healing replacement every 3 days and initially wet wound environment, with the creation of optimal microenvironment to achieve cure.

multifunctional membrane: membrane or product used with the main component of honey in combination with natural plants (fenugreek seeds) and chemicals (acetic and policresuleno acid), with antimicrobial properties and debridement, that promote granulation-epithelialization of complex wounds and Burns.

Clinical results: data that guide evaluation of the healing process of the wound, and in particular the formation of granulation tissue and / or epithelial tissue in the wound bed, and complications such as infection, bleeding or pain.

difficult to heal chronic wounds: They are considered pressure ulcers, vascular, arterial and traumatic.

In patients with chronic wounds (over 4-6 weeks duration), several factors impede the healing process at the wound bed, including concurrent disease and biochemical imbalances.

In studies of 2003, Moore mentions that it is essential to differentiate normal healing and scarring unresponsive, requiring different approaches and justified by the physician in making decisions treatment. I

This has been demonstrated by Phillips et al, who concluded: "Large ulcers, long-lasting and slow to heal after 3 weeks of optimal therapy, are unlikely to rapid healing, and could benefit from alternative therapies" .2

This view is also supported by Sheehan et al, in studies of diabetic foot ulcers, and indicate that over a period of four weeks is possible to distinguish between ulcers that heal and not heal, and predict the likelihood of complete healing in a period 12 weeks.3

Research published by the European Wound Management Association (EWMA) in the document 'Hard-to-heal wounds: a holistic approach' uses the concept of complexity of the wound. It is recognized in this document that "it is important early recognition of slow healing, and recognize the complex combination of factors that are involved in the healing process, both inside and outside wound" .4

Despite its widespread acceptance, gauze dressings are not without disadvantages. Patent Colin Marshall et al (WO 2001091681), is the following observation: "for example, frequent changes of such dressings are often accompanied by discomfort to the patient, since normally some sticking occurs to the wound or exudate thereof. in addition, the gauze type dressings do not protect the wound from extraneous bacteria nor control balance favorable to healing appropriate moisture. the gauze is not without remaining and depositing them on the surfaces of the wound it is considered undesirable. "5

Articles and texts of recent magazines and expert opinions, support the principle of moist wound healing, but in practice the use of gauze, predominantly as wet to dry dressing, does not guarantee that environment.

The concept began to change dressings passive and active dressings in terms of modifying the wound bed, now occupy an important place in the process of curación.7

Recent advances in the techniques of wound dressing, combined with a better understanding of the physiology of healing, have made it possible to customize such care. Optimized dressings reduce pain, decrease morbidity and improve healing times.

There are several new methods and products that have emerged in the last decade that have helped this constant need for improvement in wound care.

This involves investigating what may be the most effective and reasonable protocols to guide and direct care actions such chronic and complex lesions, and incorporate advanced and effective technology with the latest scientific knowledge and solutions at low cost, in order to achieve the most effective result.

Identifying factors delayed healing provides information on the need to implement interventions adjuvants, in addition to routine care at an early stage, and also to determine realistic outcomes for patients and guide decisions on alternatives.

Specifically, to assess the progress of healing of patients with chronic wounds or poorly healing, this randomized clinical trial was conducted to obtain evidence of the effectiveness of intervention advanced treatments (Membranes Multifunctionals), compared to the conventional approach using traditional cures (wet dressings dry gauze), for local wound care.

In our hospital, this is the first randomized trial comparing principles regarding local wound care in patients with chronic or difficult to heal wounds, traditional cures (wet to dry dressings) with advanced treatments (Membranes Multifunctionals).

This study provides an understanding of a new type of procedures that allows the practical treatment of these wounds, in the outpatient setting.

METHODOLOGY

a comparative assessment of 380 patients was conducted with chronic or difficult to heal in a hospital (Cures Clinic Outpatient Department of Surgery at Roosevelt Hospital in Guatemala City) between January and October 2014 wounds.

The study was approved by the Medical Ethics Committee of the Hospital.

Eligible subjects, according to the criteria of inclusion and exclusion, with description by the Principal Investigator included each patient and family goals and methods of the study and also provided and explained the informed consent form.

All patients signed this form vital for inclusion in the study element.

Eligible patients were recorded, and the reasons for exclusion. He is including any patient who abandoned or lost during the course of the study, was recorded in the appropriate form.

The criteria for inclusion and exclusion were:

INCLUSION CRITERIA:	EXCLUSION CRITERIA:
People over 18 years, both sexes.	Women with pregnancy or breast feeding.
Patients with signing the informed consent	Altered levels of consciousness for any reason.
Skin ulcer with a maximum of 15 cm ²	nutritional deficiencies.
Skin ulcer duration equal to or greater than 90 days of evolution.	malignant lesions in the wound bed.
Commitment to address monitoring wound care on an outpatient basis.	Use of steroids or immunosuppressive drugs.
	Diabetes mellitus or uncontrolled hypertension.

randomization: Patients were randomized, according to the sequence of presentation of new cases: the subjects were in odd cases, for advanced treatments Membranes Multifunctionals and even cases traditional cure (wet to dry dressings).

procedures:

Treatment: Local treatment of wounds was performed on average three times a week for advanced method and ten for the conventional method (sometimes twice a day in the latter) by nurses, whom the principal investigator gave training sessions on materials before starting the study, which by prior use in Cures Clinic Outpatient Surgery Department of Roosevelt Hospital are the practical knowledge of this staff.

Study material: In 1891 Johnson & Johnson began producing sterile surgical dressings sterilizing cotton yarns and threads, after which the gauze has become the most widely used surgical dressing, and it is undoubtedly familiar to the staff hospital.⁹

Multifunctional membrane under the trade name Bio-Film® this new dressing based of honey in combination with natural plants (fenugreek seeds) and chemicals (acetic acid and policresuleno), with antibacterial properties, it promotes granulation-epithelialization of wounds and burns complex, extremely rapidly.

Particularly this product has four basic properties to repair injured tissues:

Low pH for microbial control the local	Assistance autolytic debridement (with donation humidity)
Regulating the production of exudates	Promotion of healthy granulation tissue and growth of new blood vessels

The composition of the purified, with pH of 3.5, the product has been used successfully in acute and chronic injuries, including highly exuding, such as extensive lesions of the abdominal wall, chronic ulcers of the limbs, infected wounds with necrotic tissue wounds and burns partial thickness, showing no secondary or side effects of importance, showing optimal tolerability and safety with continued use for extended periods.

The product can remain in place for long periods (up to seven days), reducing the frequency of parts, and also eliminates the patient's pain and suffering of such drawbacks; However, when used in highly exudative lesions or other clinical reasons, the bandage may have to be changed more frequently.

Study materials received by the patients were provided by the Healing Clinic Outpatient Department of Surgery at Roosevelt Hospital, because these products are generally used in wound care at the clinic.

reviews:

The main outcome of interest was the percentage of wounds healed after 12 weeks, in connection with the formation of granulation tissue and / or epithelial tissue in the wound bed, with measurement during 4 periods of data collection (beginning four, eight and twelve weeks).

Secondary outcomes included assessing the safety and adverse events, and evaluation of symptoms reported by patients were included, and clinical signs observed by the physician.

Tracing:

Local wound care continued according to randomisation, until complete wound healing or 12 weeks of follow-up was achieved. The principal investigator supervised nursing care and injuries, visits each outpatient, and verified using dressings and adverse effects every two weeks.

Wound healing:

It was performed by visual assessment on the basis of the modified table Houghton and colleagues¹⁰, which included evaluation of: size, type and amount of necrotic tissue, type and amount of granulation tissue.

A each assigned a number from 0 to 4, then the five components were counted to obtain the total score of the wound, with the total possible scores from 0 to 24, with zero representing a completely healed ulcer.

The reliability and sensitivity were determined by the by a single evaluator previously indicated (table modified Houghton and colleagues¹⁰) and measures rule (maximum width and maximum length of the wound) during the study period visual assessments.

For security, the assessment of patient-reported symptoms and clinical signs observed by the physician included.

RESULTS

January to October 2014, 380 eligible patients were selected and randomized 190 patients in each group.

129 patients (92 in the group of wet to dry dressing and 37 Membrane Multifunctional) not completed the study for noncompliance / drop protocol. They remained in the study 251 patients for monitoring, and the time set for data collection was at weeks 4, 8 and 12.

Discontinuation of therapy due to lack of compliance by the patient, painful changes and frequent in the dressings of wet to dry gauze and other causes in the treatment group Membrane Multifunctional traumatic dressing.

Baseline characteristics, according to Table I above: age range, area and depth of the ulcer, wound location, ulcer duration, and comorbid conditions and etiologies were quite similar in both treatment groups.

Table I: Baseline demographics and patient characteristics of the wound of 380 randomized patients

	Membrane Multifunctional group (n = 190)	Gauze blankets Group (N = 190)
Sex	F: 116 (61%) M: 74 (39%)	F: 101 (53%) M 89 47 (%)
Age range	(35-75) Average age: 55	(37-72) Average age: 51
Etiology	Diabetes - 118 Venous Insufficiency - 31 Others- (arterial, pressure ulcers) -47	Diabetes - 103 venous insufficiency - 39 Others- (arterial, pressure ulcers) -42
Location of the wound	Feet - 108 (57%) Leg (lower) - 37 (19%) Trochanteric - 13 (7%) Sacras- 32 (17%)	Feet - 127 (67%) Leg (lower) - 22 (12%) Trochanteric - 12 (6%) Sacras - 29 (15%)
Wound duration	3-6 months -21 (11%) -169 +6 months (89%)	31 months 03/06 (16%) -159 +6 months (84%)
Diameter range of the lesion	14 cm ²	10 cm ²
withdrawals	Failure / drop - 37	Failure / drop - 92

Source: Cures Clinic Outpatient Department of Surgery Roosevelt Hospital Clinical Records.

Table 2 Total number of patients randomized and patients who completed treatment.

Group	# patients	# Completed study	Percentage
Multifunctional membrane	190	153	81%
Wet to dry dressing	190	98	52%

Source: Cures Clinic Outpatient Department of Surgery Roosevelt Hospital Clinical Records.

Table No. 3 Replacement healing frequency (per week)

Group	Number of Cures per week
Multifunctional membrane	3
Wet to dry dressing	10 *

* Some cases required two cures a day.

Source: Cures Clinic Outpatient Department of Surgery Roosevelt Hospital Clinical Records.

On average, 3 weekly changes of dressing Membrane Multifunctional and 10 changes dressing gauze dressings wet dry were performed for necessary twice daily in this group.

Table 4. Efficiency in the formation of granulation tissue in chronic or difficult to heal the wounds 4-week evaluation.

Effectiveness (4 weeks)		Multifunctional membrane		Wet gauze dressing dry	
0-6 points	Suitable	52	37.3%	eleven	11.2%
12.06 points	Regular	24	12.7%	16	16.3%
12 to 18 points	Inadequate	31	20.0%	3. 4	34.7%
18-24 points	Deficient	46	30.0%	37	37.8%
Total		153	100%	98	100%

Source: Cures Clinic Outpatient Department of Surgery Roosevelt Hospital Clinical Records.

In the first evaluation, at four weeks, the treaty with the membrane Multifunctional group had completely or close to close in 50% of cases, compared with 28% of wet to dry dressings healed.

Table 5. Efficacy in the formation of granulation tissue and / or epithelial tissue in the wound bed, in chronic wounds or poorly healing at 8 weeks assessment.

Efficiency (8 weeks)		Multifunctional membrane		Wet gauze dressing dry	
0-6 points	Suitable	77	50.3%	twenty	20.4%
12.06 points	Regular	32	20.9%	29	29.6%
12 to 18 points	Inadequate	35	22.9%	30	30.6%
18-24 points	Deficient	9	5.9%	19	19.4%
Total		153	100%	98	100%

Source: Cures Clinic Outpatient Department of Surgery Roosevelt Hospital Clinical Records.

In the second evaluation at eight weeks, the treaty with the membrane Multifunctional group was completely cured or close close in 71% of cases, compared with 50% of wet to dry dressings.

Table 6. Efficacy in the formation of granulation tissue and / or epithelial tissue in the wound bed at 12 weeks assessment.

Effectiveness (12 weeks)		Multifunctional membrane		Wet gauze dressing dry	
0-6 points	Suitable	98	64.0%	24	24.5%
6-12 points	Regular	32	20.9%	33	33.7%
12 to 18 points	Inadequate	16	10.5%	27	27.5%
18-24 points	Deficient	7	4.6%	14	14.3%

Source: Cures Clinic Outpatient Department of Surgery Roosevelt Hospital Clinical Records.

In the final assessment at twelve weeks, the treaty with the membrane Multifunctional group had healed or close close in 85% of cases, compared with 58% of the wet to dry dressings.

Table No. 7 Side effects caused by membrane Multifunctional

Adverse effects	Case No.
Odor (Patient's subjective symptoms)	17
excessive secretion (Patient's subjective symptoms)	eleven
Dermatitis (Objective signs determined by the Principal Investigator)	3
Total	31

Source: Cures Clinic Outpatient Department of Surgery Roosevelt Hospital Clinical Records.

The most obvious problem with using Membrane Multifunctional was the presence of areas of redness in three cases, during the initial use of the dressing (dependent wound exudate) and representing 0.02% of the total 153 patients.

DISCUSSION

Our study confirms what has been reported in multiple studies, using gauze bandages wet to dry cure, can re-injure the wound after retiro.¹¹

Accordingly, the Centers for Medicare and Medicaid in long-term care, establish that repeated use bandage wet to dry, in healing ulcers, can damage the granulation tissue and can lead to bleeding excessive and increasing time curación.¹²

Guides pressure ulcer of the Association of Medical Directors of the United States indicate that wet to dry dressings are not supported because they bind and remove vital tissues when removed and tend to be dolorosos.¹³

It was very evident in our study, 92 patients neglect (48% of initially randomized) in the group of wet to dry dressing, by painful and traumatic frequent dressing changes.

Sibbald et al., Mention that the wet-dry wound healing is a painful and traumatic method can cause substantial discomfort and altered wound bed as well as a poor adherence by paciente.¹⁴

Lim et al., They mention that the bandage wet gauze dry causes tissue destruction and various injuries in each dressing change, which ultimately delays healing, and explain that derived from evaporation of the salt solution, the fabrics are dried, thereby preventing the migration and proliferation celular.¹⁵

Ovington, described as "gauze standard of care is erroneously considered by the disruption of angiogenesis to the removal of dressings and increased risk of infection by frequent changes and prolonged inflammation, as good reasons to abandon this technique" traditional".¹⁶

✠ The international survey of the European Association of Wound Management (European Wound Management Association), indicated that the gauze is more likely to cause pain, and causes more adhesions to the wound bed, and also no longer recommend its use as the best practice.¹⁷

In acute analysis and radicals, Fleck in his article written in 2009 on the use of gauze bandage, makes the reader the following questions: "They are appropriate only for mechanical debridement can cause pain and suffering to the patient each dressing change.. and impaired wound bed cause hypoxia, vasoconstriction, cooling and destruction. removing dried bandage significant wound dispersed bacteria in the air ".¹⁸

In this sense, the author writes: "If you answered all of the above," you are correct. Why, then, most of the wounds are bandaged with this type of archaic and barbaric treatment? "

In his conclusion, he writes and asks: "Why wet-dry We can not sit idle and complacent when there are other options and that evidence has shown a cost and positive clinical result Let's help abolish this archaic treatment of wounds a. . once and for all Repeat after me: "The wet-dry method needs to die!" ¹⁸

As for our results, at four weeks, significant progress was observed in the treated group Membrane Multifunctional as it had healed or close close in 50% of cases, compared with 28% of wet to dry dressings.

The latter agrees with the reference cited by Sheehan and collaborators arriba³, which over a period of four weeks is possible to differentiate between ulcers that will not heal and heal, and predictive possibility of complete healing at 12 weeks.

Sussman also mentions that. "It is understood that some patients may never heal because of the pathophysiology basic process of the disease, and the inability to alter some or all of the main factors influencing the wound did not heal, however even in the most extreme cases, good wound care can be a big help to minimize the worst effects of such chronic wounds. " ¹⁹

In the present study the notorious failure / discontinuation in patients with wet dressings dry (48%), by changes of painful dressing and often traumatic, and in this sense, the membrane Multifunctional observed, turn out to be a solution easier to use in wound care.

Clinical wound care, the World Health Organization reported that the average rate of non-adherence to treatment of patients is 50%, among those living with chronic diseases, which may include the problem of a chronic wound .twenty

Jin, et al recommend incorporate the use of high quality products. It recognizes that the complexity of multiple cures and product failure threaten patient adherence to treatment. And they wrote: "A specialty product well designed can cost initially more than a generic product, but the cost can be recovered through better adherence to treatment of the patient, a more effective use of the products and faster healing." twenty-one

At a time when the health system strives to focus on clinical excellence, compliance has become a significant factor to achieve a positive treatment outcome.

This implies that the person is motivated enough to stick to a prescribed treatment due to a perceived benefit or result.

Failure, on the other hand, suggests that the person is not motivated sufficiently to adhere to a scheme, and does not receive a benefit or a positive result of therapy.

CONCLUSIONS

This study demonstrated that the membrane Multifunctional leads to improved and accelerated regeneration and epithelialization of tissues in patients with chronic wounds difficult to heal, compared with the method of healing bandage wet to dry.

The need for frequent changes in the method of wet to dry dressing gauze, involves added risk to the patient and wound by additional treatment procedures; use of longer interventions and material resources (dressings, gauzes, cleaning equipment, sterile equipment, etc.) and promotes non-compliance / drop treatment by patients.

RECOMMENDATIONS

It is recommended that further experimental studies that demonstrate the effectiveness between the traditional method of healing and advanced healing with multifunctional dressing in a larger population, using the original assessment tool for photographic (PWAT), by three experienced clinicians blinded to treatment group , to accurately assess the appearance of the wound.

These factors can be identified and examined in future studies and provide a rating system even more reliable

LIMITATION

There are limitations to this research should also be recognized as being conducted in a single hospital, and lack of additional data due to loss of follow-up of participants.

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APPENDIX

HOUGHTON MODIFIED SCALE USED IN THE STUDY

Description	Evaluation	Punctuation
Necrotic tissue type	0 = None visible 1 = non-viable tissue, white / gray and / or yellow sloughing nonadherent 2 = slightly tacky sloughing Yellow 3 = black eschar, soft, slightly tacky 4 = black eschar firmly adhered	
Amount of necrotic tissue	0 = None visible 1 = <25% covering the wound bed 2 = 25% to 50% covering the wound bed 3 => 50% and <75% covering the wound bed 4 = 75% A100% covering the wound bed	

Skin color covering the wound	<p>0 = normal Rosa or ethnic group</p> <p>1 = bright red</p> <p>2 = white or gray or hypopigmented paleness</p> <p>3 = dark red or purple</p> <p>4 = Black or hyperpigmented</p>	
Granulation tissue	<p>0 = intact skin wound or partial thickness</p> <p>1 = bright red and fleshy; 75% to 100% of the wound covered and / or tissue growth</p> <p>2 = bright red and fleshy; <75% and> 25% of the wound</p> <p>3 = pink and / or dark and / or filler ≤ 25% of the wound</p> <p>4 = No granulation tissue present</p>	
epithelialization	<p>0 = 100% cover wound surface intact</p> <p>1 = 75% to <100% of the wound covered and / or epithelial tissue extends> 0.5 cm in the wound bed</p> <p>2 = 50% to <75% of the wound covered and / or epithelial tissue extends> 0.5 cm in the wound bed</p> <p>3 = 25% to <50% of the wound cover</p> <p>4 = <25% of the wound covered</p>	
Total score		