

RESEARCH

Mobile Application and Advanced Analytics in Wound Care: Variable Predictors of Wound Evolution in a Public Intermediate Hospital

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Abstract

Background: Chronic wounds are one of the most frequent complications of pathologies such as diabetes mellitus, peripheral neuropathy, atherosclerosis, infections, among others. Early diagnosis and effective treatment is required to avoid later complications, leading to infections or even amputations. The early assessment of this type of wound is crucial when it comes to detecting possible patterns that require special and rapid care.

Methods: In the present study, 2,750 wound samples consisting of image and anamnesis taken by Hospital Santa Creu de Vic with the Clinicgram application over three years were captured. The evolution of the area as an indicator of healing was observed between the different characteristics obtained from the application. Two ratios are calculated corresponding to the healing rate and healing time, which refer to the percentage of wounds that reduce their area 50% after four weeks. It has also been taken into account that necrotic tissue does not increase and the wound does not become infected. These ratios were compared between etiologies and treatments and the different criteria of the Resvech scale. A Kruskal-Wallis test, and ANOVA was performed to assess whether there are statistically significant differences between the groups of samples corresponding to the calculated ratios between the different Resvech parameters. P-values of less than 0.05 in all of them indicate that the groups come from statistically different distributions.

Results:

Strong correlation between size, edges and exudate with healing results was observed in patients with venous ulcers (24.44%) and traumatic ulcers (29.73%). Mean of 4 weeks of healing time for wounds between 64cm² and 100cm², 5 weeks for damaged edges and 3 weeks for wounds with presence of epithelial tissue.

Conclusion: Wound assessment variables in elderly patients are correlated and impact on healing process. We can determine specific patient profiles to avoid complications.

Keywords: healing rate; chronic wounds; evolution predictors

Content

Text and results for this section, as per the individual journal's instructions for authors.

Introduction

Skin ulcers are an important cause of morbidity and mortality everywhere in the world [1], and occur due to a number of causes, including diabetes mellitus [2], peripheral neuropathy, immobility, pressure, arteriosclerosis, infections, and/or venous insufficiency [3]. Ulcers are lesions that fail to undergo an orderly healing process and produce functional and anatomical integrity in the expected time (4 weeks to 3 months). This is usually due to an underlying pathology that prevents or delays healing. Ulcers have a major impact on the patient's life, causing a reduction in the quality of life in physical, emotional [4], and social dimensions. According to the international definition from the National Pressure Ulcer Advisory Panel (NPUAP) [5] and the European Pressure Ulcer Advisory Panel (EPUAP), a pressure ulcer (PU) is a localized lesion of the skin or underlying tissue, in general above a bony bulge, as a result of pressure, where shear combination pressure is included [6]. A number of contributing factors or confounding factors are associated with both the cause and maintenance of ulcers. In addition, care of these wounds requires the expenditure of human and material resources, and generates a great economic impact. For these reasons, complex wounds such as ulcers are considered a major global problem. Difficult-to-heal wounds comprise different types of injuries: Pressure Ulcers (PPL), Lower Extremity Ulcers (Arterial, Venous, Diabetic Foot [7]), Neoplastic Ulcers, and others with atypical clinical features, histology, localization, and resistance to standard therapies [8]. Treatment of complex wounds is often difficult as the disparity in treatment criteria, and the multitude of care products, can lead to forgetting the cause. Thus, healthcare professionals are the key to achieving healing and improving the management of material and human resources. In the healthcare sector, large amounts of data are generated and can be used to improve treatment and diagnostic procedures, as well as research. However, access to these data by health professionals requires tools that are able to store, transform, and represent the data, and facilitate the interpretation of this information. According most relevant assessment scales [4], [9], [10], the following variables are most relevant when assessing the severity of an injury:

- Area measurement: area in cm² of wound.
- Depth affectation: presence of bone, tendons or muscle.
- Type of Edges: Teriulceral skin condition, Presence of erythema, edema, eczema; whole, lacerated, or macerated.
- Tissue classification: Type of wound tissue, presence of erythema, cramps, epithelialization, granulation, or necrosis.
- Type of exudate: Quantity (abundant or scarce) and type (hemorrhagic, purulent, or serous).
- Signs of infection: Pain, odour, presence of biofilm, etc.

A procedure for capturing, transforming, and representing data using a chronic wound patient management platform called Clinicgram is proposed 2. In each clinical case of this study, information has been collected about the patient, their wounds, and the treatments applied. The traceability of each of these clinical cases has been studied using the available retrospective information, and the related information has been represented in order to extract key indicators for chronic wound management. This platform has given us the ability to quickly and effectively extract indicators of interest for both managers and clinicians in the healthcare sector.

Create a centralized system for helping decisions can provide patient-specific assessments that support clinical decisions, improve prescribing practices, reduce medication errors, improve primary and secondary prevention delivery, and improve adherence. The aim of this study is to figure out the most relevant indicators in wound care that help clinicians assess healing time, healing rate, treatment cost-efficiency, and usage of treatments.

1 Materials and Methods

1.1 Data and sample

Figure 1 shows an overview of the study protocol conducted with a total of 2,750 wound samples taken by 10 nurses for analysis during the study from January 2018 to November 2021. A selection of data from 400 patients from a reference centre over a period of three years, was made. Specifically, we extracted data from patients, clinical cases, and samples.

The patient data corresponds to the patient's anamnesis, including previous pathologies and those preceding the complication of chronic wounds. The clinical case data provide the etiology, wound type, and level of care. The samples correspond to the consultation records of patients attending the hospital for follow-up of their clinical case, from which information can be extracted on the wound itself – assessed using the Resvech [9] scale – as well as the measurement of the area, the type of tissue, the presence of infection, and the treatment applied.

Acceptance criteria:

- Age 70 or older, of any gender and ethnicity.
- Be able to tolerate changes of position and turns for up to 10 minutes comfortably.
- Have an existing skin lesion whose length and width can currently be measured with a ruler and a perpendicular camera focus.
- Skin lesion is external, and site of the external wound fits completely within the field of vision and does not involve an edge of the body, leaving some of the hidden parts.
- Individual capture and analysis process for each wound.
- No device or treatment will hide the location of the external wound.
- Informed consent signed.

Non-acceptance criteria:

- Cannot comfortably tolerate changes of position for up to 10 minutes (for each area of the external wound from which images are obtained).
- Cannot be positioned so that images can be taken at approximately 90 degrees perpendicular to the wound.
- Undergoing therapies or treatments that cannot be safely suspended long enough to conduct an imaging session according to the center's policy.
- Has a skin lesion with excessive exudate that cannot be controlled during the imaging session. Excessive drainage can hide the characteristics of the external wound.
- The external lesion surrounds an edge of the body or cannot be fully visualized within the field of view.

- From the visual assessment, the existing external wound cannot be clearly distinguished from other conditions at the site of the external wound (for example, the rupture or deterioration of the surrounding body surfaces due to other conditions such as cancer or other types of wounds make it impossible to determine the edge of the external wound)
- No signed informed consent has been provided.

1.2 Variables

In order to capture and analyse the data, a digital tool was introduced into clinical practice. Clinicgram is a clinical image management tool with the aim of providing healthcare professionals with a platform where they can enter data and images of patients with chronic wounds, facilitating the process of diagnosis and treatment monitoring (see Figure 3). Clinicgram allows healthcare professionals to enter patient data, such as the clinical case of each patient and the images taken in consultation. Through machine learning and artificial intelligence techniques, Clinicgram then determines the criticality of the patient's condition through the Resvech scale and measurable characteristics of the image, such as the area of the wound [11], the percentage of necrotic tissue, slough and granulated tissue [12], and the presence of infection. In addition, the type of applicable treatment can be chosen according to clinical criteria [13].

1.2.1 Healing rate

The first calculated ratio required for this study corresponds to the healing rate and has been calculated through the area and percentage of necrotic tissue type returned by Clinicgram with wound imaging, together with the Resvech scale criterion corresponding to the presence of infection. According to [14], a 50% reduction in wound area after four weeks is considered as positive wound evolution, so the number of wounds that have halved in area and had neither increased necrotic tissue nor infection after four weeks from the first recording was calculated and defined as the healing rate. The healing rate was compared between the different etiologies and prescribed treatments of the wounds recorded in Clinicgram.

1.2.2 Healing time

The second ratio calculated corresponds to the time it takes for wounds to decrease in area by 50%. Thus, for each evaluation criterion of the Resvech scale, the average healing time of the different values that each of these criteria can take has been compared.

1.3 Statistical Analysis

To homogenize the data collected, a database was created using Mysql server. Data obtained were analysed using Matlab Statistics software R2021a. Quantitative variables that followed the normal distribution were expressed as absolute and relative frequencies, medians, arithmetics means, and standard deviations with a confidence interval of 95%. For qualitative variables, absolute percentages were calculated. (NEW) The non-parametric method of ANOVA called Kruskal-Wallis test were used to analyse the relationship between the ratios through components of Resvech

scale. It does not assume a normal distribution of the residuals. Then the independent variables correspond to Resvech scale values and dependent variables are the calculated ratios healing rate and healing time. P-values lower than 0.05 were considered that the groups comes from different distribution and there is a statistically significant difference.

2 Results

A total of 400 patients with a median age of 70 years, and a total of 1,347 records, were included in the present study. According to [14], a 50% change in ulcer area after 4 weeks of observation is a robust predictor of healing at 12 weeks . Thus, patients with a positive wound evolution were selected, and the elapsed time of wound area reduction to half of the measurement captured at baseline was calculated. The number of wounds that resulted in a 50% reduction in wound area after 4 weeks from the start of wound recording, was also calculated. Results are shown according to wound characteristics, etiologies, and treatments.

The data were obtained from the Clinicgram application in tabular form, and correspond to patient, clinical case, and sample data, as listed in Table 1.

400 clinical cases were analysed with an average of 3.37 samples per clinical case – a sample being a temporal record of the wound. From each record, information on the wound area was assessed based on the Resvech 2.0 scale. The treatments and etiology of each wound were also assessed. Due to the fact that the reference health centre where the study was carried out is a primary care centre, most of the wounds correspond to venous ulcers ($n = 90$), followed by pressure ulcers ($n = 83$), and diabetic wounds ($n = 46$) (Table 2).

2.1 Calculations and Statistics

The percentage of wounds that reduced their area by half within 4 weeks, was calculated according to their etiology and the treatment applied. The calculated percentages were adapted to the number of wounds per etiology and treatment recorded during the study. Furthermore, the time taken to halve the wound area was calculated based on the different characteristics of the Resvech 2.0 scale (Table 3).

We tested whether the medians between the different groups (differentiated by the evolution of the wound area in the samples) are statistically significant, whereby p-values greater than 0.05 would indicate that there is no significant difference between the medians of the groups. Since the data do not follow a normal distribution, and the n of each group varies in each case, the Kruskal-Wallis test and ANOVA was performed. Matlab was used for this purpose. The results indicate that the medians of the wound healing time between the different groups of the Resvech scale have significant differences (p-value less than 0.05 in all cases).

2.2 Healing rate by etiology

Of all etiologies, traumatic ulcers have the highest healing rate of 29.73%, followed by venous ulcers with a rate of 24.44% (Figure 4). In contrast, diabetic ulcers have the least favourable evolution with 6.5% of ulcers halving in size after 4 weeks.

2.3 Healing rate by treatment

The treatments used to compare wound healing rates were selected according to those used in the reference centre where the study was conducted. The best performing treatment was inhibitors of metalloproteases with a healing rate of 26.27%, which is used for the treatment of venous ulcers and was used on a total of 15 samples collected during the study (Figure 5). Other treatments such as polyurethane foam + silver (25%), multilayer bandage (22.41%), or elastic bandage (23.07%), which have applications in a wider range of chronic wound etiologies, also had good effectiveness. The most commonly used treatment is polyurethane foam, which has a total of 217 uses and an effectiveness of 10.6% (Figure 5), and is used for pressure ulcers, traumatic ulcers, diabetic ulcers, and venous ulcers.

2.4 Healing time by size

Wound area reduction time is shorter in those wounds where the initial wound area is between 64 and 100 cm² with approximately 4 weeks of mean, and has relatively lower data variability (Figure 6). In contrast, greater variability is found in those wound area classifications of <4cm² and 4 < 16cm² with medians between 7-8 weeks for healing. All records take less than 10 weeks to heal but there are no records for areas greater than 100cm².

2.5 Healing time by borders

There is a high variability (healing time between 5 and 19 weeks), with outliers, in the area-reduction time of those wounds that have bounded edges. As seen in Figure 7, those records with damaged or fuzzy edges have a shorter healing time (mean healing time of approximately 5 weeks). The majority of records have bounded edges (n = 119), so the results may be affected by this factor.

2.6 Healing time by tissue type

The results of the time it takes for the wound to reduce its area by 50%, show that epithelial tissue is the fastest to close with a mean healing time of approximately 3 weeks. Most of the records correspond to granulated tissue (n = 102) resulting in a higher number of outliers and variability of data (healing time between 5 and 17 weeks) (Figure 8).

2.7 Healing time by exudate

Exsudate is considered important for the supply of proteases, such as matrix metalloproteinases (MMPs) and polymorphonuclear elastase (PMN) [15], which facilitate wound healing. Figure 9 shows that wet and saturated wounds have a shorter closure time with a mean healing time between 4 and 6 weeks. Almost no records (n = 5) were obtained with leaking exsudate, which would be the worst case scenario.

2.8 3.7. Healing time by depth

The depth of the wound is a difficult characteristic to diagnose, as auxiliary techniques are required to get inside the wound. At first glance, it is unlikely to be available. Figure 10 shows that those wounds that have healed intact skin have the shortest healing time with only two weeks of mean to heal followed by muscle involvement with approximately 5 weeks of mean. The majority of samples recorded

are at the dermis/epidermis level and in the subcutaneous tissue, which is a good setting for wound healing.

3 Discussion

The transformation of raw data into valuable data, i.e. from information to knowledge specially in wound care [16], will provide both the clinician and his or her organisation with objective tools that will enable them to carry out clinical practice more quickly and safely [17]. It will be possible to analyse the data from different perspectives – macro, meso, and micro. This increase in productivity and accuracy in decision-making will undoubtedly improve the quality of patient care. In terms of efficiency, the tool like Clinicgram, or others [18, 19, 20, 21, 22, 23] provides capabilities for the practical analysis of the cost-effectiveness of different treatments, as well as the generation of ratios that can reveal the real use of these treatments and their related costs.

Being able to capture all this data through the mobile application allows health-care organisations to analyse the data and turn it into real knowledge and actions. Benefits include: having systems for detecting events that may require clinical action by the professional, determining possible correlations between these events and the risk of negative evolution of the wound, analysing the impact of the management of these events on improving healing time in patients with chronic wounds, and alerts according to the level of specialisation of the professional to take clinical measures or consider patient referral. Having the data accessible will also allow the creation of patient profiles according to the critically of the case, help alert the professional of high-risk patients, and help the professional anticipate the best treatment.

The present work explains how the use of artificial intelligence can have a direct positive impact on healthcare, and specifically on wound care. From a point of care perspective, it provides the ability to perform faster and safer automatic assessments, and is an element of consultation and decision support for the healthcare professional. Moreover, of special relevance are the results obtained when analysing the set of data it provides; not only will anamnesis or clinical history data [24] (eg. diabetes, hypertension, BMI, etc.) be analysed, but also objective elements will be used, which, based on computer vision, provide unstructured information that is often difficult to evaluate by the human eye (eg. percentage of tissue in the wound, dimensions, colourimetry, etc.). The impact that the results can have both on the organisation [25] of a health system and on day-to-day life in terms of efficiency, cost-effectiveness, quality of care, quality of life of the patient, and quality of nursing work, is enormous.

A limitation of this study is the number of complete assessment of each sample into the database. Manual handling of the data is also a limitation as it requires more time and increases the risk of human error. Also, the mobile application is working integrated into the general clinical practice and sometimes the rigor required to analyze the data cannot be followed and established in the study protocol. In this study, the concept of healing rate, quite similar to [26], has been discussed including additional variables in addition of wound area [27]. Other variables [9] have been studied, such as tissue classification, affected depth, type of edges, exudation and signs of infection.

4 Conclusions

This study aims at expanding the knowledge that is needed to improve wound care competences in order to improve wound healing time and patient satisfaction.

In light of the presented results, the first conclusion we can draw is the suitability of incorporating a data collection system, such as Clinicgram, into clinical practice. It is true that a modification in clinical practice will be required to incorporate the tool into a nurse's day-to-day work, but considering the time required for data collection and the short- and long-term benefits it can provide, it is considered worthwhile to make such a modification. Without such a tool, it would not be possible to analyse the data obtained.

According to the results, the evolution of the chronic wound can be affected by some parameters with greater relevance. At the level of the wound itself, the analysis in this study shows that those wounds that have certain qualities can accelerate the healing process. The number of wounds with a positive evolution differs depending on etiology and the treatment applied. However, the results may be affected by the bias in the number of samples per group analysed. Additionally, in the case of treatments, there are some treatments that are complementary to others, so they should be evaluated as a whole.

To conclude, we can see from the resulting analyses that of all the characteristics analyzed in the assessment scale, the one that is most critical to wound healing is the type of wound edge since a bounded wound may take approximately 6 weeks longer to heal than a diffuse or damaged edge. In all other cases the median remains the same although in cases such as exudate and the type of tissue in the wound bed can make the difference in healing time almost 4 weeks on average.

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Ethics approval and consent to participate

The study was conducted in accordance with the Declaration of Helsinki and was approved by the Ethics Committee of the Consorci Hospitalari de Vic (2019093 / PR224).

Competing interests

D. Reifs, the author of this paper, is co-founder of Skilled Skin SL and owner of the proposed digital health solution used in this study to capture and process data.

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Figures

Figure 1 Protocol Study

Figure 2 Application captures. From left to right: List of studies, Samples over time, Detail sample with measurement, Resvech scale, Tissue classification.

Figure 3 Global and system architecture (App, AI Algorithms and Insights Analytics module).

Figure 4 Percentage of wounds with a 50% reduction in area in 4 weeks from the start of the registry, according to etiology.

Figure 5 Percentage of wounds with a 50% reduction in area in 4 weeks from the start of the registry, according to the applied treatment.

Figure 6 Time in weeks to reduce the wound area by 50%, according to wound size.

Figure 7 Time in weeks to reduce the wound area by 50%, according to wound borders.

Figure 8 Time in weeks to reduce the wound area by 50%, according to tissue type.

Figure 9 Time in weeks to reduce the wound area by 50%, according to its exudate.

Figure 10 Time in weeks to reduce the wound area by 50%, according to wound depth.

Tables

Table 1 Data captured from the application

Patients	Clinical cases	Samples
Creation Date	Creation Date	Creation Date
Gender	Etiology	Area
Age	Typology	Tissue Classification (necrotic, slough and granulated)
		Edges type
		Exudate

Table 2 Number of wounds registered by etiology

Aetiology	Num. of wounds registered
Arterial ulcer	33
Suture dehiscence	16
Hematoma	18
Mixed Ulcer	23
Others	15
Pressure Ulcer	83
Surgical Ulcer	13
Traumatic Ulcer	37
Diabetic Ulcer	46
Venus Ulcer	90

Table 3 Resvech 2.0 characteristics selected

Wound Size	Tissue type	Exudate	Edges	Depth
0 cm ²	Closed / healing	Moist	Delimited	Involvement subcutaneous tissue
< 4cm ²	Granulation tissue	Dry	Fuzzy	Impact of the dermis-epidermis
4 < 16 cm ²	Epithelial tissue	Saturated	Damaged	Involvement of bone or tissue attached
16 < 36 cm ²	Necrotic tissue or spheres	Wet	Spoiled	Muscle involvement
36 < 64 cm ²	Necrotic (dry black)	Leaking	No distinguishable	Intact skin
64 < 100 cm ²	Hypergranulation			
> 100 cm ²				