Diagnostic Accuracy of the Photographic Imaging in the Granulation of Diabetic Ulcers Using Color Segmentation

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Abstract: The study aimed to determine the accuracy, sensitivity, and specificity of a study of non-invasive diagnostic photographic imaging tests concerning the pathological anatomical study in the granulation of non-infected diabetic ulcers treated conventionally or as an adjuvant in a diabetic foot unit in Trujillo (Peru). The design was a diagnostic test that was carried out with 29 types 2 diabetic patients with 45 non-infected diabetic ulcers comparing the direct observation of a granulation area by photographic image as a diagnostic test in evaluation concerning standard by pathological anatomy through a punch type biopsy. The photographic image was obtained using a CATS61 smartphone analyzed by red and black color segmentation using ImageJ software. The study was authorized by the ethics committee of the Faculty of Medicine of the National University of Trujillo. The statistics were made using the SPSS and EPIDAT software. Diabetic ulcers presented an average of 3.03±2.39 cm long, 2.26±1.62 cm wide, a predominance of type 2 ulcer (deep non-bone) by Wagner in 73.3%, predominance of type A ulcer (with peripheral neuropathy) according to the University of Texas in 60%. The diagnostic tests for photographic imaging presented a sensitivity of 90%, a specificity of 33.3%, and an accuracy of 61.6%. This study showed very high sensitivity, low specificity, and regular accuracy in detecting granulation.

Keywords: ***Diabetic ulcer, Photography, Imaging.***

I. INTRODUCTION

The International Diabetes Federation considers diabetes to be one of the greatest global health emergencies of the 21st century, with over 425 million adults currently suffering from it [1]. The frequency of recurrence of diabetic ulcers has remained unchanged from 2002 to the present with a prevalence of 21.8-22.2% [2]. Diabetic ulcers cause poor quality of health in adult diabetic patients [3].

Diabetic ulcers are wounds that do not heal after 3 months of evolution. Their pathogenesis is hyperglycemia, chronic inflammation, macrocirculatory dysfunction, microcirculatory dysfunction, autonomic-sensory neuropathy, hypoxia, and bacterial load [4]. The wound healing process has three stages such as inflammation, proliferation, and epithelialization [5].

Non-invasive imaging techniques for chronic ulcers are photographic imaging, hyperspectral imaging, thermographic imaging, laser Doppler imaging, and focal microscopy [6]. Photographic imaging allows the subsequent reflectance and scattering of light reflected from the skin surface to cause visualization and identification of surface structures [7].

The evaluation of the state of the ulcers by photographic image is performed when the image captures the red-pink, white-yellow and black colors that correspond to granulation, sloughing, and necrosis respectively [8]. The methodology for analyzing the photographic image of ulcers is based on color segmentation [9].

Previous studies on photographic imaging of diabetic ulcers were only similar in subject matter using segmentation in India [10]; in the United States [9]; and in the Netherlands [11]. There are no photographic imaging studies with diagnostic test design about histological studies.

The identification of new techniques, identification of more objective findings, and quantification of the usefulness of photographic imaging in the healing process justified the objective to calculate the accuracy by sensitivity and specificity of photographic imaging concerning anatomical histological study in the granulation of non-infected diabetic ulcers with conventional or adjuvant treatment in a diabetic foot unit.

II. MATERIALS AND METHODS

A. Design and Variables

The design of this study was a cross-sectional and simple diagnostic test. The variables of this study were the evaluable test for photographic image granulation of ulcers and the standard test for histological study. Photographic image ulcer granulation had a positive indicator of the presence of the red zone of the diabetic ulcer processed by color filters in ImageJ analysis software. The standard test had a positive indicator of the presence of fibroblasts, extracellular matrix, and blood vessels in the microscopy study.

B. Population, Sample, and Sampling

The study population was all type 2 diabetic patients with foot ulcers. The sample size result using data from a pilot study and a specific statistical methodology [12]. The sample was chosen by non-probability sampling by experts. The sample was drawn from patients who presented the following inclusion criteria: type 2 diabetics, over 18 years of age, any gender, submitted to the collection form, and with a foot ulcer that had healed for 4 weeks. The exclusion criteria were acute or critical lower limb ischemia and infection. The unit of analysis was the granulation area of each diabetic ulcer.

C. Collection Technique

The data collection instrument consisted of clinical examination, photographic image, and histology results that were validated.

A CATS61 smartphone with 16 megapixels, 4619 x 3464-pixel resolution, and adjustable focus was used in the evaluation of the photographic imaging. The region of interest was the ulcer and the imaging capture was at 20 to 30 cm perpendicular to the surface of the ulcer using a laser point, details in figure 1. The image analysis was performed by ImageJ that was free software for Microsoft Windows in JPG format.

The analysis of photographic imaging was based on the adaptation of two studies [8,13]. The aforementioned analysis began with the identification of the edges of the ulcer, the identification of red, yellow, and black colors, then the application of HSB filters (hue, saturation, and brightness), and finally the color filters for the red and black color. The photographic imaging test was positive if the color red was present by the analysis software and this was negative if the color black appeared.

The biopsy was obtained by using a 2 mm diameter skin punch needle intralesional to the point identified as image granulation using biosecurity rules. The biopsy was obtained in the granulation area that the physician identified by direct observation.

The histological evaluation of the biopsy was performed by conventional microscopy of the lamina prepared with hematoxylin and eosin considering the histological criteria that were present, quantity, and disposition by a field concerning fibroblasts, chronic inflammatory infiltration, extracellular matrix, and blood vessels [14]. The histological test was positive if there were at least 3 criteria evaluated for presence and quantity.

The figure 2 shows a case of a 48-year-old diabetic patient with an uninfected right hallux dorsal ulcer treated with conventional healthcare who was evaluated by segmented photographic imaging and histological study test.

D. Procedure

The evaluation site was a diabetic foot unit in the north coastal city of Trujillo, Peru. The technique of obtaining the clinical data and images was performed by a nurse and trained technician. The analysis of the photographic imaging, the biopsy, and histological analysis was performed by the researcher, the trained surgeon, and the medical pathologist respectively.

E. Statistical Analysis and Ethical Aspects

Descriptive statistics were performed for general sample characteristics, photographic imaging, and histology using SPSS 22. Analytical statistics were performed using contingency tables for photographic imaging versus histology tests. The sensitivity, specificity, and accuracy calculations were performed using EPIDAT 4.4. This study has obtained the approval of the ethics committee at the National University of Trujillo. The informed consent was performed to all patients and data confidentiality was respected.

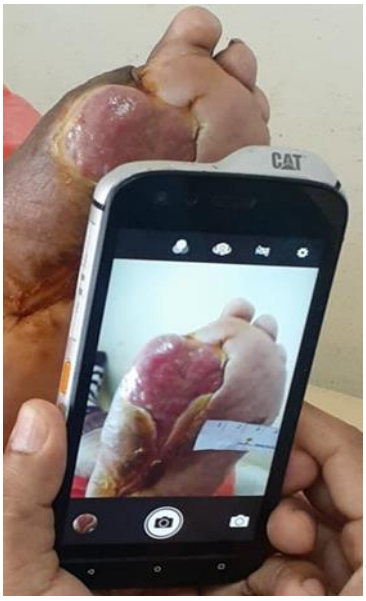

Figure 1. the approach of diabetic ulcer using a CATS61 smartphone.

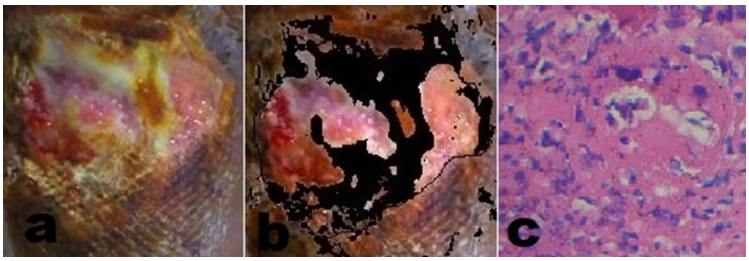

Figure 2. A case of diabetic ulcer where "a" is the standard photographic imaging, "b" is the segmented photographic imaging and "c" is the histological imaging.

III. Results

The patients recruited and evaluated were 29 patients with uninfected diabetic ulcers. The predominant characteristics were male gender in 62.1%, mean age was 60.83 ±13.38 years, time of illness over 5 years was 69%, treatment of oral diabetes with 96.5%, the regularity of treatment was 44% and presence of a history of amputation was in 31%. The number of ulcers was unique in 75.9% (22 patients), two ulcers in 13.8% (4 patients), and three ulcers in 17.3% (5 patients). The clinical examination of the 45 diabetic ulcers had the following characteristics: the right affected side in 64.4%, time of evolution in 2.21 ±1.69 months, peripheral neuropathy in 75.6%, and peripheral arterial disease in 40%. The average length and width of the ulcer were 3.03±2.39 cm and 2.26±1.62 cm respectively. The classification of ulcers according to Wagner-Meggitt was type 1 (superficial), 2 (deep non-bony), 3 (deep bone) in 22.2%, 73.3%, and 4. 4% respectively and the classification of ulcers according to the University of Texas were typed A (without vascular or infectious lesion) and type C (vascular lesion) in 60% and 40% respectively and characteristics of the ulcer are shown in table 1. The

contingency table of diagnostic tests to identify granulation in diabetic ulcers evaluated by photographic imaging test versus histological test was shown in table 2. The sensitivity, specificity, and accuracy were 90%(CI95:74.4-96.5), 33.3%(CI95:15.2-58.3), and 61.65 (CI95:44.8-77.4).

Table 1. Characteristics by clinical examination in 45 non-infected foot ulcers evaluated by photographic imaging and histological test in 29 diabetic patients.

Characteristics of the ulcer	Parameter	F (%)
General anatomical zone	Forefoot	31(68.9)
	Midfoot	6(13.3)
	rearfoot	8(17.8)
Specific anatomical zone	Hallux	19(42.2)
	Lesser toes	12(26.7)
	Metatarsal	4(8.9)
	Medial arch	6(13.3)
	Lateral arch	4(8.9)
Deep	Surface	3(6.7)
	Deep non-bone	13(28.9)
	Deep bone	29(64.4)
Type of secretion	Serous and bloody	27(60)
	Purulent	18(40)
Predominant healing	Red	33(73.3)
	Yellow	12(26.7)

Table 2. Contingency table of 45 diabetic ulcers evaluated by photographic imaging test versus histological test in 29 diabetic patients.

Test	Positive histology	Negative histology	Total
Positive photographic imaging	27	10	37
Negative photographic imaging	3	5	8
Total	30	15	45

IV. Discussion

Diagnostic accuracy is the degree of a test that measures what it is supposed to measure [15]. The sensitivity is the possibility to present the condition when it is truly present and the specificity is the possibility to don't present the condition when it is truly absent [16]. Diagnostic tests are used for the presence of certain diagnostic conditions in the clinical setting and this study was the granulation of this condition 17].

This study shows three cases of false negatives that are explained when these ulcers do not show granulation because they didn't arrive at the minimum red color tone to be identified as positive by the photographic imaging. The ten cases of false positives located in the center of the ulcer were red color but microscopically other tissue was found; the explanation was because this part is reddish non-granular tissue and this area doesn't occur the granulation [18].

The sensitivity of our study was high but the specificity was low i.e. the photographic imaging test is very good at identifying granulation when it exists and bad at identify-ing non-granulation when it does not. The accuracy of our study was moderate i.e. the photographic image test is regularly accurate in identifying granulation by the red color that is explained by the increase in blood capillaries [19]. This diagnostic test using photographic imaging could not be compared with another study because there wasn't a similar study concerning design.

The photographic image of this study has been analyzed by a segmentation methodology which was laborious because the software was not customized for this study but feasible. The physical basis of the photographic image is based on the optics described by digital visible light images and they have a limitation due to the visible wavelength don't identify characteristics related to oxygenation or birefringence as in the other optical methods [20]. The red color of the photographic imaging has provided in this study their presence, location, and intensity that can be used in future studies.

A limitation of this study was not using personalized analysis software and strength was the easy handling of the smartphone.

V. Conclusion

This original study of diagnostic tests that evaluated the photographic imaging test for the identification of granulation of non-infected diabetic ulcers presented a high, low, and moderate sensitivity, specificity, and accuracy respectively. This photographic imaging test is a biomedical adjunct for the diagnostic and treatment aid in diabetic ulcers.

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