

Lidocaine controls pain and allows safe wound bed preparation and debridement of digital ulcers in systemic sclerosis: a retrospective study

Francesca Braschi^{1,2} · Francesca Bartoli^{1,2} · Cosimo Bruni^{1,2} · Ginevra Fiori^{1,2} ·
Claudia Fantauzzo^{1,2} · Lucia Paganelli^{1,2} · Amato De Paulis³ · Laura Rasero⁴ ·
M. Matucci-Cerinic^{1,2}

Received: 18 August 2016 / Revised: 25 August 2016 / Accepted: 10 September 2016 / Published online: 29 September 2016
© International League of Associations for Rheumatology (ILAR) 2016

Abstract In Systemic Sclerosis (SSc), digital ulcers (DU) are painful, difficult to heal, and frequently infected. To reduce the risk of bacterial infection and to prevent chronicity, it is essential to carefully remove necrotic tissue from DU, with maximum patient comfort. Debridement, although very efficacious, is invasive and causes local pain: lidocaine is a local anesthetic commonly used as to fight pain during debridement procedures. The aim of the study was to evaluate the efficacy of lidocaine 4 % in pain control during debridement procedure of DU in SSc. One hundred eight DU characterized by pain Numeric Rating Scale (NRS) >3/10 before starting the procedure were treated with lidocaine 4 % (lidocaine cloridrate 200 mg in 5 ml of injecting solution). Pain was measured with NRS (0–10) before starting debridement, after 15 min of lidocaine application and at the end of the procedure. In DU, in respect to baseline (mean NRS 6.74 ± 2.96), pain after application of lidocaine 4 % for 15 min was significantly lower (mean NRS 2.83 ± 2.73) ($p < 0.001$). At the end of the procedure, pain control was still maintained and significantly

lower (mean NRS 2.88 ± 2.65) in respect to baseline ($p < 0.001$). No systemic adverse event due to topical lidocaine were observed. In SSc, topical application of lidocaine 4 % significantly reduces pain, allowing a safe debridement procedure, thus improving the management of DU.

Keywords Lidocaine · Pain · Systemic Sclerosis · Ulcers

Introduction

In Systemic Sclerosis (SSc), at least 50 % of patients develop digital ulcers (DU), which are usually chronic, painful, infected, and at risk of developing serious complications such as gangrene, osteomyelitis, and amputation [1–3].

In DU, wound bed preparation is of pivotal importance and the further debridement of necrotic or compromised tissue is a fundamental step to foster healing, prevent chronicity, and reduce the risk of bacterial infection [4].

Debridement is a part of the wound bed preparation which may obtain the removal of foreign material and devitalized or contaminated tissue from or adjacent to the lesion. This is important because it is well known that tissue necrosis and slough may release cytokines that can frequently determine pain and worsen the status of DU.

Debridement can be achieved through surgical, enzymatic, autolytic, mechanic, or biological methods. When the removal of devitalized tissue in DU is performed by the use of scalpels and surgical instruments, the procedure is usually painful. Therefore, it is essential to carefully remove necrotic tissue while maintaining the highest patient comfort possible. Lidocaine was demonstrated to be a viable option, and it is commonly used as a local anesthetic to control pain during debridement [5, 6]; it is indicated for venipuncture,

F. Braschi and Francesca Bartoli have contributed equally to this work

✉ Francesca Bartoli
francesca.bartoli19@gmail.com

¹ Department of Experimental and Clinical Medicine, University of Florence, Florence, Italy

² Department of Geriatric Medicine Division of Rheumatology AOUC, University of Florence, Florence, Italy

³ Department of Translational Medical Sciences and Center for Basic and Clinical Immunology Research (CISI), University of Naples Federico II, Naples, Italy

⁴ Department of Public Health AOUC, University of Florence, Florence, Italy

intravenous cannulation, and minor surgeries. Topically, it is used to relieve itching or burning of the skin; otherwise it can be injected directly in the tissues in minor surgery, especially dentistry. Currently, no data indicating the dosage of lidocaine that should be employed to control DU pain during debridement both in general and SSc population is reported in literature [7, 8]. For this reason, we reviewed the charts of SSc patients submitted to surgical and/or autolytic debridement of hands DU to evaluate the efficacy of lidocaine 4 % in controlling pain during the procedure.

Patients and methods

The clinical charts of SSc patients, classified with ACR/EULAR criteria and subset according to Leroy et al. [9, 10], with DU of the hands, followed up from 1 January 2013 to 30 June 2013 in the Division of Rheumatology, University of Florence, submitted to routine weekly debridement, according to wound bed preparation methodology, were retrospectively reviewed. Patients were enrolled in the study if pain assessed with Numeric Rating Scale (NRS) was >3 before the removal of the dressing; DU derived from digital pitting scars and calcinosis were excluded, according to a previously proposed classification [1]. Before every procedure, patients were informed about the task of the debridement and about the use of anesthetics to control local pain. In the case of patients with multiple DU, the procedure was performed separately on each lesion, without time overlapping. In our practice with SSc patients, DU were treated with galenic formulation of lidocaine 4 % solution vials (each lidocaine vial contained lidocaine chloride 200 mg in 5 ml of injecting solution) applied on the lesion for 15 min before debridement through a gauze soaked with the solution. According to our practice, lidocaine 4 % 1 ml was used on DU <0.5-cm diameter, 2 ml on DU 0.5–1-cm diameter, and 3 ml on DU >1-cm diameter. Lidocaine 4 % solution vial was chosen as supplied routinely by the pharmacy of our hospital. We decided to maintain the lidocaine for 15 min as applied on a skin lesion and not on intact skin, where a more prolonged exposure is recommended, supposing a more rapid absorption due to epithelial membrane

damage. Pain was measured with NRS (0–10) after the removal of the dressing, 15 min after lidocaine application (and considered satisfactory if reduced of minimum 40 % from baseline) and then at the end of the procedure.

Informed consent was obtained from all patients prior the procedure and the study was approved by our local ethical committee.

Data were inserted in a Microsoft Excel datasheet; ANOVA for repeated measures, with Bonferroni's multiple comparison test for post hoc analysis, was used for the evaluation of efficacy. Chi-square was used to evaluate differences between groups in the binomial variables. Data analysis was performed using SPSS 12.0 statistical package for Windows and results are presented as mean \pm standard deviation for continuous variables, with $p < 0.05$ considered as statistically significant.

Results

The clinical charts of 92 SSc patients with DU of the hands were reviewed: debridement was performed by surgical and autolytic methods to clean the wound bed [4]; mean duration of debridement procedure excluding lidocaine application was 20 min (Fig. 1). Seventy-six out of 92 patients fulfilled inclusion/exclusion criteria: according to skin involvement extent, 69 were limited cutaneous SSc (lSSc) (63 women and 6 men, mean age 61 ± 6 years) with a total of 94 DU and 7 diffuse cutaneous SSc (dSSc) (6 women and 1 man, mean age 63 ± 4 years) [10] with a total of 14 DU. After 15 min of lidocaine application, we found a reduction of pain in 100/108 DU (92.59 %); the remaining 8/108 DU required an additional time exposure to lidocaine and were therefore excluded from the analysis.

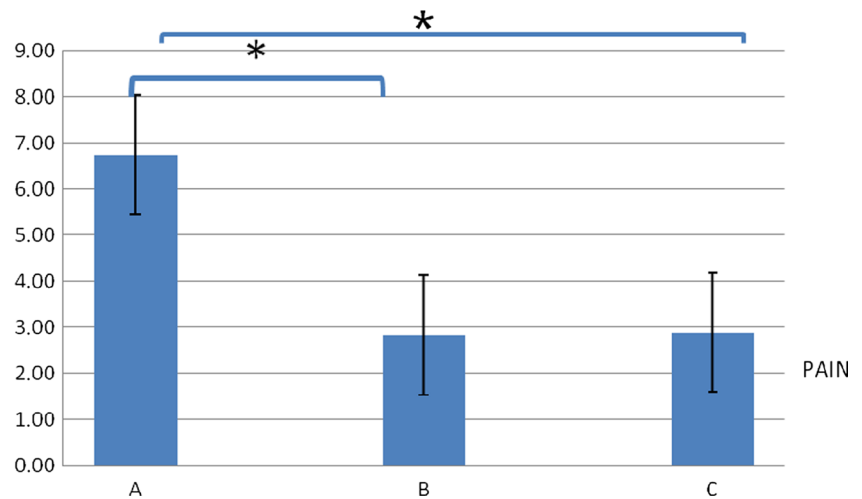
In respect to baseline (mean NRS 6.74 ± 2.96), pain after lidocaine application was significantly lower (mean NRS 2.83 ± 2.73 , $p < 0.001$). At the end of procedure, pain control was still maintained and significantly lower than baseline (mean NRS 2.88 ± 2.65 , $p < 0.001$), despite the invasive procedure of debridement with scalpels (Fig. 2).

The topical application of lidocaine 4 % did not elicit any systemic severe adverse event, but local discomfort (burning



Fig. 1 DU before (*1a*) and after (*1b*) debridement performed after lidocaine application. The lesion has a large and deep area of dry necrotic tissue which needed more than one debridement procedure. The lesion healed after 23 weeks of treatment (*1c*)

Fig. 2 NRS pain (mean \pm SD) before (a) and after 15 min of lidocaine application (b), and at the end of procedure (c)
* $p < 0.001$



and itching) was observed in 28/108 DU (25.92 %); in all cases, the time to resolution of local event was lower than 3 min. The 8 DU excluded from the whole analysis, due to the extra time needed to get anesthesia, were more severe: 2 derived from gangrene, 4 from extended necrosis, 2 with chronic infection. Despite the delay, we have observed results similar to the larger group (mean NRS before lidocaine 6.50 ± 2.20 vs mean NRS after lidocaine 2.75 ± 1.03 vs mean NRS after debridement 3.12 ± 1.12 , $p < 0.001$).

Discussion

In this study, we showed that the application of lidocaine 4 % on DU can successfully control pain and allow a safe debridement. To our knowledge, this is the first study evaluating the topical use of lidocaine in standard concentrations to reduce pain during the procedure of debridement in SSc patients affected by a painful complication like DU, apart from a single case report [8]. Previously, in a placebo-controlled, multicenter, double-blind study, it was shown that lidocaine 2 % applied locally before debridement on leg ulcers of vascular etiology reduced pain significantly [5].

Our data show that the local application of lidocaine 4 % elicits a significant reduction of pain in the majority of SSc patients, thus favoring a painless and safe debridement procedure. Debridement allows the nurse to carefully remove eschars, fibrin, necrotic tissue, and clean the DU borders. Obviously, the debridement procedure is an invasive maneuver which reduces the risk of bacterial proliferation and other complications and is pivotal for significantly reducing DU time to healing.

The cleaning of DU with debridement is known to allow the reduction of drug use as well as medical and nursing activities, thus significantly lowering the costs needed to heal DUs.

A faster control of pain may have a positive impact on direct costs for specialist care and help to significantly spare the frequent use of nonsteroidal anti-inflammatory drugs and

analgesics [6]. In addition, it can reduce indirect costs related to the loss of working days and psychological stress due to pain and disability, also supported by a good safety profile.

Regarding anesthesia timing, only 8/108 DU enrolled in our study required lidocaine application for more than 15 min to reach an effective pain control, thus undergoing a delayed debridement later in the session. These patients carried more severe DU or suffered from a chronic history of uncontrolled pain. The severity of DU may likely be one of the reasons that have provoked a delayed effect of lidocaine. In practice, this suggests that we may encounter patients with severe DU which may need a special care with extra time to get anesthesia.

In conclusion, our study provides the evidence that local lidocaine 4 % solution may significantly control DU pain thus allowing a safe debridement procedure. For this reason, the use of lidocaine 4 % could be therefore usefully translated in every day clinical practice to facilitate the work of nurses on DU and alleviate the discomfort of SSc patients.

Further studies with higher number of DU are warranted to confirm our preliminary data.

In the future, it would be interesting to extend the investigation of this procedure in DU of the lower limbs in SSc as well as in other rheumatic diseases.

Compliance with ethical standards Informed consent was obtained from all patients prior the procedure and the study was approved by our local ethical committee.

Disclosures None.

References

1. Amanzi L, Braschi F, Fiori G, Galluccio F, Miniati I, Guiducci S et al (2010) Digital ulcers in scleroderma: staging, characteristics and subsetting through observation of 1614 digital lesion. *Rheumatology (Oxford)* 49:1374–1382

2. Denton CP, Krieg T, Guillevin L, Schwierin B, Rosenberg D, Silkey M et al (2012) Demographic, clinical and antibody characteristics of patients with digital ulcers in systemic sclerosis: data from the DUO registry. *Ann Rheum Dis* 71:718–721
3. Matucci-Cerinic M, Krieg T, Guillevin L, Schwierin B, Rosenberg D, Cornelisse P, Denton CP. (2016) Elucidating the burden of recurrent and chronic digital ulcers in systemic sclerosis: long-term results from the DUO Registry. *Ann Rheum Dis* 75(10):1770–1776
4. European Wound Management Association (EWMA) (2004) Position document: wound bed preparation in practice. Medical Education Partnership Ltd, London
5. Rosenthal D, Murphy F, Gottschalk R, Baxter M, Lycka B, Nevin K (2001) Using a topical anesthetic cream to reduce pain during sharp debridement of chronic leg ulcers. *J Wound Care* 10:503–505
6. Woo KY, Abbott LK, Librach L (2013) Evidence-based approach to manage persistent wound-related pain. *Curr. Opin. Support. Palliat Care* 7(1):86–94
7. Briggs M, Nelson EA, Martyn-St James M. (2012) Topical agents or dressing for pain in venous leg ulcers. *Cochrane Database Syst Rev* 11:CD001177
8. Ozgocmen S, Kaya A, Coskun BK (2006) Topical lidocaine helps reduce pain of digital ulcers in systemic sclerosis (scleroderma). *Clin Rheumatol* 25(3):378–379
9. Van den Hoogen F, Khanna D, Fransen J, Johnson SR, Baron M, Tyndall A et al (2013) Classification criteria for systemic sclerosis: an American college of rheumatology/European league against rheumatism collaborative initiative. *Ann Rheum Dis* 72:1747–1755
10. Leroy EC, Black C, Fleishmajer R, Jablonska S, Krieg T, Medsger TA Jr et al (1988) Scleroderma (systemic sclerosis): classification, subsets and pathogenesis. *J Rheumatol* 15:202–205