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No-Option Chronic Limb-Threatening Ischemia: What can we do to Save Limb?

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Abstract

The aim of this study is to describe the characteristics, the management and the outcome of a series of patients with no-option Critical Limb Ischemia (CLI) treated with a conservative multidisciplinary combined approach including best wound care, NPWT and dermal substitutes. The primary end was limb salvage and 1-year amputation-free survival. The secondary end was mortality and healing time of lesion. Between January 2016 and January 2021, 76 patients with no options CLI were admitted. In 14 patients, there was a failure in distal revascularization with a persistent CLI after the procedure. In 58 patients, revascularization was not feasible. Despite the persistent CLI, a group of patients of this cohort obtained no progression of CLI, complete wound healing treated with surgical debridement or distal amputation and application of NPWT in association with dermal substitute. Any superimposed infection was treated with antimicrobials. Pain was controlled with analgesics. Overall limb was saved in 72% of the cases. A 1-year survival was 84%. Use of NPWT, dermal substitutes combined with a conservative foot surgery with an approach with minor amputation in patients with no-option CLI may save patient limb and life.

Keywords: Amputation; No-option CLTI; Critical ischemia; Limb salvage

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Introduction

Chronic or non-healing vascular ulcers are lesions that persist despite adequate wound care and do not respond to standard treatment [1]. These wounds are painful and have an unfavorable prognosis mainly so when treatment is not appropriate. Standard wound care gives usually partial benefit with a high recurrence rate. In more recent years innovative Dermal Substitutes (DS), such as Porcine Derived Dermal Substitute (PDDS) and Alloplastic Skin Substitute (ASS) became available for clinical use [2,3]. These biomaterials promote tissue regeneration and shorten healing time. They are simple to apply onto ulcers and cause a surprising relief of pain, thus improving patient compliance. Despite these advantages their role in repairing chronic vascular ulcers has not been fully investigated so far and data available in the literature are scanty.

PDDS, we used to be made of a porcine tendon-derived atelocollagen layer and a silicone film. This biomaterial integrates with host tissue, favors migration of fibroblasts into the atelocollagen matrix and promotes the formation of a dermis-like tissue. Alloplastic Skin Substitute (ASS) we used has elastic and plastic properties and is highly permeable to oxygen and water vapor, features that make it valuable tool to treat epidermal and dermal lesions as well [4].

The purpose of the present study was to evaluate safety and efficacy of PDDS and ASS as innovative treatments for non-healing vascular wounds of lower limbs.

Material and Methods

We performed a retrospective review using our database that included 82 patients seen for non-healing vascular ulcers of lower limbs from January 2019 to June 2021 at our Vascular Surgery Unit. Non-healing leg ulcers were defined as a lesion that do not respond to standard treatment (disinfection with antimicrobial solution and dress with normal gauze) or advanced treatment (greasy medicated gauze or hydrocolloid) and persist for at least 3 months. Medical therapy of the underlying disease, including anticoagulants anti-platelet drugs and statins, was continued. Diagnosis was based on clinical features, ABI measurement and Doppler ultrasonography. Inclusion criteria were the presence of venous, diabetic (40% located below the ankle), autoimmune or ischemic ulcers defined as non-healing without response to standard and advanced care and

with no surgical option. Particularly patients with ischemic lesions were affected by critical limb ischemia and defined as patients with femoro-popliteal-tibial occlusion not suitable for revascularization with ABI <0.6.

Exclusion criteria were silicone allergy, hypersensitivity to proteins of animal origin, wound infection or uncontrolled bleeding. Wound surface was measured using dedicated specialized smartphone application while pain was evaluated using Visual Analogue Scale (VAS). Patients were followed up for 6 months post-treatment.

The primary endpoint was healing of ulcer and complete pain relief within 3 months post-treatment.

Procedure

All surgical procedures were performed under aseptic conditions. After debridement and hemostasis, wound was rinsed with super-oxidized solution. PDDS was modelled according to the shape and the size of the wound and eventually it was hydrated with few drops of sterile saline before use. After that it was applied on the ulcer without staples in order to minimize perilesional trauma and covered with a non-adherent dressing made of greasy gauze. Bandage was then applied with moderate compression and local medication was changed every 5 days. In instances when wounds were exudating or blood was present the use of fenestrated PDDS allowed an efficient drainage. When the collagen layer was replaced by new tissue, typically after 7 to 14 days, the silicone film came off spontaneously and ulcer healed by secondary intention.

Healing of PDDS-treated lesions that were deep and long lasting was speeded up by the use of ASS. This was applied after engraftment of PDDS.

Superficial non-healing wounds were debrided, washed with super-oxidized solution and then treated with ASS alone. This was applied over the wound area in all directions. The dressing was then slightly stretched, air bubbles were removed and ASS was protected by covering it with a greasy gauze. Additional ASS dressings were overlapped as needed in order to cover large lesion areas.

Some typical pictures of skin wounds taken by us before and after treatment are also presented. This study respect ethical requirements, each patient gives us a written informed consent.

Results

Thirty-eight subjects, males 53%, age 65 ± 8.5 years, suffering from non-healing lesions often involving deep structures (21% with tendon involvement, 2% with bone exposure, 50% involving fascia) were treated with the porcine-derived dermal substitute. Twenty-nine patients, males 48%, age 68 ± 6.2 years, with wide and often recurring lesions were treated first with the above PDDS and after 7 to 12 days with the ASS. The remaining 15 cases, males 27%, age 61 ± 14.3 years, seen for superficial non-healing wounds were treated with ASS alone. Demographic details are presented. Etiology of lesions was ischemic/diabetic in 35 (43%) cases, venous in 41 (50%) and autoimmune in 6 (7%). Wound median length was 7 months (range 3-18) wound median area, cm^2 12.25 (7.5-31.5) and VAS score, mean ± SD 8.2 ± 1.7.

Fifty percent of cases were due to chronic venous insufficiency and two-thirds of them had post- thrombotic syndrome. Thirty-five of cases (43%) were due to ischemia and 6 (7%) to autoimmunity. Length of vascular ulcerative disease spanned from 3 to 18 months and medium wound area was a little bit higher than 12 cm^2. VAS score indicates that pain was a severe one. Outcome of treatment is given. More than 90% of patients cured irrespective of treatment they had received and of etiology of lesions. Medium time to healing was approximately one month for those treated with PDDS alone or with PDDS and ASS and it was shorter, approximately three weeks, for cases treated with ASS. Four patients improved as indicated by a 45% to 62% reduction of ulcer size. Two subjects, one PDDS and one ASS, failed therapy and remained unchanged. Pain disappeared in all cases within two to seven days of treatment and analgesics were no longer needed. No adverse events occurred in any of the three treatment groups either under therapy or during follow-up.

Discussion

We presented a large case series including 82 patients suffering from chronic vascular non-healing leg ulcers treated with PDDS or with the sequential application of PDDS and ASS or with ASS alone. The retrospective analysis of data indicates that therapy was very effective and well tolerated irrespective of the baseline features of the disease. Results appear encouraging if one keeps in mind that chronic non-healing leg ulcers are challenging to physician for several reasons. Indeed, the underlying disease should not be overlooked [5], pain is often severe and frequent and prolonged use of analgesics exposes to side effects with renal failure being most harmful, history is long-lasting and in turn complications are frequent, patient becomes unable to sleep and QOL may be highly impaired.

It is our opinion and experience that if wounds are deep, sometimes reaching the underlying bone, use of PDDS is most indicated. When lesions are wide, deep and tend to recur application of ASS some days after PDDS favors complete healing in a shorter time. It is well known that even superficial vascular wounds may not heal for a long period. In such instances, we found that application of ASS alone is very effective. It is pertinent to underlie that high clinical efficacy of PDDS depends on its properties, application is easy, shaping is optimal, the wide range of types and sizes available on market (single or double layer, the latter being fenestrated and/or reinforced) enable one to select the product based on wound characteristics, growth of a new tissue is favored, bacterial contamination is prevented from occurring by the silicon film, inflammatory and immune responses are negligible due to PDDS biological properties [6,7]. The above-mentioned characteristics all account for clinical effectiveness of PDDS. On the other hand, ASS is safe, has physical properties that favor healing of wide, often recurring, wounds. Indeed, multiple dressings may be used in an overlapping position in order to cover wide injured areas. Availability of innovative DS, such as PDDS and ASS, enables one to avoid autologous skin transplant. Therefore, they are an especially valuable option when an autoimmune disease prevents from performing transplantation.

It is difficult to compare our results with those of others because data on treatment of vascular lesions with innovative DS are scanty.

Vascular leg ulcers remain challenging even for expert physicians because they are difficult to treat, are painful and patient compliance becomes poor over time. The data we presented indicate that chronic vascular ulcers can be treated successfully with innovative DS, such as PDDS and ASS, which both proved safe and highly effective. Moreover, the study was limited by small and heterogeneous population, retrospective design, monocentric experience. Future studies on already unmet needs will be entirely welcome.

Conclusion

Chronic vascular leg ulcers remain a major problem for management. The data of present study indicate that Dermal Substitutes (DS) such as PDDS and ASS are safe and effective therapeutic tools for their treatment, irrespective of the etiology and of wound characteristic.

Surgical approach is minimally invasive, application is easy, functional and cosmetic outcomes are satisfactory, patient QOL is much improved. In some clinical settings, the sequential application of PDDS and ASS may facilitate healing. Most important, treatments such as those we used, may avoid skin transplantation and remain a valuable option when transplantation cannot be performed.

References

1. McCarty SM, Percival SL. Proteases and delayed wound healing. Adv Wound Care (New Rochelle) 2013;2:438-47.
2. Ehrenreich M, Ruszczak Z. Update on tissue-engineered biological dressings. Tissue Eng. 2006;12(9):2407-24.
3. Macri L, Clark RA. Tissue engineering for cutaneous wounds: Selecting the proper time and space for growth factors, cells and the extracellular matrix. Skin Pharmacol Physiol. 2009;22(2):83-93.
4. Nischwitz SP, Popp D, Shubitidze D, Luze H, Zrim R, Klemm K, et al. The successful use of polylactide wound dressings for chronic lower leg wounds: A retrospective analysis. Int Wound J. 2021.
5. Sallustro M, Marrone A, Florio A. A case report on treatment of nonhealing leg ulcer: Do not forget the underlying disease. Int J Low Extrem Wounds. 2021;22(1):1534734621999029.
6. Suzuki S, Matsuda K, Isshiki N, Tamada Y, Ikada Y. Experimental study of a newly developed bilayer artificial skin. Biomaterials. 1990;11(5):356-60.
7. Sallustro M, Polichetti R, Florio A. Use of porcine-derived dermal substitutes for treatment of nonhealing vascular leg ulcers: A case series. Int J Low Extrem Wounds. 2020;21(3):1534734620945561.