



## **Experience in Using Human Stem Cell Solution Extracted from Adult Stem Cell Culture Media (Pure 99.9 % Origin Cell) in the Treatment of Necrobiosis Lipoidica Diabeticorum (NLD)**

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**Received Date: October 24, 2022**

**Published Date: November 01, 2022**

**Abstract**

**Background and objectives:** *Necrobiosis lipoidica (NL) is an inflammatory granulomatous skin disease closely associated with diabetes mellitus specially type I (NLD) and seen more often in women.1*

*Necrobiosis lipoidica (NL) can be associated with other diseases like sarcoidosis, rheumatoid arthritis, autoimmune thyroiditis and inflammatory bowel disease.3*

*Although the etiology and pathogenesis of the disease is still controversial, its believed that dermal microangiopathy has an important role.*

*Though there are multiple therapeutic options, no treatment for NLD has shown consistent efficacy. I report a case of a 25- years old type 1 diabetic female with a about 10- year history of a progressing non ulcerative NLD plaques. She wasn't on any systemic or topical treatment except the Insulin injections.*

**Patient and methods:** *In this case report, I investigated the therapeutic effect of intralesional human stem cell extract injection using pure 99.9 % origin cell product, in a young diabetic female patient with multiple progressing necrobiosis lipoidica lesions on her limbs.*

**Results:** *Even though the patient has a significant atrophic telangiectatic plaque that has been present for more than 10 years, intralesional injections of human stem cell extract showed significant, satisfactory improvement from the first session in terms of the color, texture, and thickness of the skin.*

**Conclusion:** *It has been demonstrated that using human stem cell extract as an intradermal injection in NLD lesions is a successful, safe, and simple strategy, giving NLD patients glimmer of hope in the therapeutic approach.*

*Using stem cell extract solution is a new alternative for treating damaged skin due to the regenerative effect on the cells.*

## Introduction

Necrobiosis lipoidica diabetorum (NLD) is a chronic inflammatory granulomatous skin disease closely associated with diabetic patients specially type I. The legs, especially shins are the most common affected sites, but other areas like upper limbs, as in my patient, can be involved. Lesions are often multiple and bilateral. The lesions start as small brown papules that gradually enlarge with progressive change in the skin texture and color. Significant central skin atrophy and telangiectasia. Ulceration may occur in 35 % of the patients.[2]

Several factors like trauma and metabolic changes can contribute to the disease onset.

## Pathogenesis:

NLD is a granulomatous disorder of the dermis, characterized by collagen degeneration and granuloma formation in the dermis, combined with thickening of the dermal blood vessels (microangiopathy).

In diabetic patients, microangiopathy occurs as a result of glycoprotein deposition on the endothelial cells lining the blood vessels resulting in blood vessels thickening. There's a theory focuses on the increased collagen crosslinking in diabetic people, which could be responsible for basement membrane thickening in NLD.

Another theory believes an antibody mediated vasculitis may initiate the vascular changes based on immunoglobulin deposition in the blood vessels walls and subsequent necrobiosis in NLD.[4]

The granuloma formation can be explained by the impaired neutrophil migration leading to an increased number of macrophages.[5]

## Treatment

The therapy alternatives that are currently available for necrobiosis lipoidica diabetorum have shown to have limited and inconsistent effectiveness. The most prevalent therapy modalities for NLD are outlined in the list below:

- The 1st line therapy includes systemic corticosteroids, intralesional or potent topical corticosteroids for early lesions.
- Topical calcineurin inhibitors.[6]
- UVA1 Phototherapy

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- Photodynamic therapy with 632 nm of red-light.[7]
- Pulsed dye Laser
- IV immunoglobulin and methylprednisolone.
- Pentoxifylline.
- Intralesional Infliximab.[8]
- Antiplatelet therapy.
- Hyperbaric O2 therapy.
- Systemic Isotretinoin.
- Cyclosporine.
- Fumaric acid esters.[9]

### Case Presentation

25 years old lady presented to my clinic complaining of a significantly large patch on the pretibial area of her right lower leg. She is diabetic on Insulin since she was 12 years old. She started to develop skin lesions very early, when she was around 15 years old. This was the biggest skin lesion but she has multiple smaller lesions were present on both lower legs, feet as well as on her hands (totally about 20 small skin lesions).

All lesions are on the extensor sides of her limbs, painless and not itchy.

She is not on any systemic or topical treatment except the Insulin injections. Regarding her skin problem, because of the experience of unsuccessful previous treatments of her father who is diabetic as well and has similar lesions on his lower legs, she gave up and didn't seek any medical advice till she presented to my clinic.

Clinical examination reveals: A significant skin disorder on the lower third of the right lower leg. It's around 6 X 5 cm well demarcated red-brown, oval, shiny plaque. Borders are slightly raised with central skin atrophy and telangiectasia surrounded by yellowish wax like shiny atrophic skin. Centrally there is a small hyperpigmented round macule.



**Figure.1.** before treatment, well demarcated red-brown, oval shiny plaque.

Raised borders with central skin atrophy and telangiectasia, surrounded by yellowish wax like shiny atrophic skin.

There are around 20 small, variable sized hyperpigmented, slightly atrophic macules scattered on the extensor surfaces of the limbs.

**Course of therapy and active ingredient:**

Pure origin cell (99,9% purity human stem cells extract) is made of stem cell culture media which cultures adult stem cell from cord blood (not embryonic stem cell). Using stem cell extract solution is a new alternative for treating damaged skin due to the regenerative effect on the cells.

The treatment session applied by intradermal injections of the dissolved origin stem cell powder, using 30 G needle in the affected skin lesion.

Unfortunately, the patient was not regular on treatment, sessions were about every 6 weeks. She received totally 3 sessions by the time of publication.

No farther treatment of any type was done.

## Result

A significant improvement in the NLD lesions, even after years of neglect, using intralesional human stem cell extract in a young diabetic lady.

Clinically the size, color, skin texture and thickness of the main lesion have significantly improved in the first follow-up, which occurred about 6 weeks later. The border started to fade.

The patient was quite satisfied.

No post-treatment adverse effects were reported. The treated area required no special care after the sessions.



**Figure.2.** After, the borders of the plaque started to fade. There is significant improvement in the size, color, skin texture and skin thickness.

## Conclusion

Necrobiosis Lipoidica diabetorum is a skin disorder that usually occurs in diabetic patients but can be associated with other diseases.

Although NL affects diabetic patients more than others, patients with normal glucose metabolism can be affected as well. The correlation between the development and progression of NLD and the poor glycemic control remains controversial.<sup>8</sup>

It impacts on the quality of life due to cosmetic visibility especially in females.

It has been strongly argued that diabetic microangiopathy underlies the pathogenesis of NLD. Many publications have laid stress on the importance of vascular occlusive changes in the lesions of NLD, and it has been suggested that it's the direct cause of tissue necrosis.<sup>10</sup>

It's important to treat the patients in early stages and monitor the advanced lesions for signs of ulceration and to decrease the potential of malignant transformation.<sup>8</sup>

Necrobiosis lipoidica diabetorum is a difficult disease to treat, the available therapeutic options are difficult to approach and have proven to produce minimal and inconsistent results. In this case report, I investigated the therapeutic effect of intralesional human stem cell extract injection using pure 99.9 % origin cell product, in a 25- years old diabetic female patient with multiple progressing necrobiosis lipoidica lesions on her limbs. In the 1st follow-up, about 6 weeks later, there is a significant improvement in the clinical picture regarding the size, color and skin texture of the main NLD lesion. The patient is glad to see the successful treatment result after years of losing hope.

Human stem cell extract solution is a new alternative for treating damaged skin due to the regenerative effect on the cells.

The application of this treatment as intradermal injection in NLD lesions has been proven to be successful, safe, easy method and providing a new hope in the therapeutic approach for NLD patients.

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