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Extraordinary Rapid Wound Healing Time in Diabetic Patients Treated with Microburst Insulin Infusion

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ABSTRACT

Importance: Non-healing diabetic ulcerations of the foot lead to amputations and premature mortality. Microburst Insulin Infusion has demonstrated an ability to accelerate healing in otherwise non-healing wounds.

Objective: To demonstrate the benefit of adding Microburst Insulin Infusion to conventional diabetic wound care to significantly decrease wound healing time.

Methods: A case series of five patients received Microburst Insulin Infusion therapy for significant peripheral diabetic ulcerations after failing conventional wound care. These five cases were treated from 4 independent Microburst Insulin Infusion clinics. Four of the wounds exceeded 6 cm². Patient charts were reviewed and relevant data was collected. All individuals in this manuscript have given written informed consent to publish these case details.

Setting: Multicenter referral clinics providing Microburst Insulin Infusion Therapy

Exposure: Microburst Insulin Infusion is an adjunctive treatment to conventional diabetic therapy performed in an outpatient clinic setting. A weight based oral glucose dose is administered while pulsatile intravenous insulin is delivered by the Bionica Microdose pump. The treatment is comprised of three 1 hour sessions and occurs up to five times a week, when the patient presents with un-healing wounds.

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Main Outcomes and Measures: Time to wound healing. A secondary outcome was failure of wound healing. Hypothesis for this study was formulated post treatment.

Results: A significant decrease in wound healing time was observed when utilizing Microburst Insulin Infusion. The mean time to complete healing was 84.2 days compared to 133 days in published literature⁽¹⁾. The patient with a foot wound measuring an amazing 228.6 cm² healed in 102 days and amputation was not necessary. There were no treatment failures in this small series. As a result of decreased healing time, there was an absence of infection and no amputations were required for these wounds.

Conclusion and Relevance: The addition of Microburst Insulin Infusion therapy resulted in a shortening of the time to healing by 49 days (7 weeks) for patients with poor response to conventional wound care. This is a 37% reduction in the time to heal thus reducing risk of infection and additional healthcare costs. The mechanism of action of Microburst Insulin Infusion in healing diabetic wounds is still unclear, but may involve an improved cellular metabolism, decreased inflammation and increased levels of Nitric oxide that enhance peripheral vascular supply and tissue healing.

Introduction

The impact of diabetes mellitus on the health of the world's population is staggering. Diabetic foot ulceration and amputation were estimated to cost U.S. Taxpayers \$10.9 billion in 2001⁽²⁾. In the United Kingdom, the corresponding figure is 252 million pounds⁽²⁾. Diabetic neuropathy often complicated by peripheral arterial dysfunction in the lower extremity can lead to ulceration and necrosis and frequently amputation. Diabetic foot ulceration occurs in 4-10% of diabetics⁽³⁻⁵⁾. Approximately 15% of diabetic foot ulcers will not heal and 5-24% will result in amputation⁽⁶⁾.

Conventional treatment for diabetic foot ulceration includes debridement of the wound, which can be accomplished by sharp debridement, enzymatic debridement, or autolytic debridement. Offloading can be done with a non-removable total contact cast. Surgical revascularization may be required in some cases. Appropriate treatment of infection

is an integral part of management of diabetic foot ulcers. We present a novel treatment that promotes and accelerates wound healing in cases not responding to conventional therapy.

Microburst Insulin Infusion is a technique that treats the end organ damage of diabetes mellitus⁽⁷⁾. This therapy is administered as an adjuvant to the patient's normal regimen of diabetic medications, either oral hypoglycemic or insulin. An oral glucose load is given to approximate the caloric intake of 2 meals (800 – 1200 calories). Microbursts of Intravenous insulin are administered by the Bionica Microdose pump, which mimics the normal secretion of insulin by the pancreas. Microburst Insulin Infusion is given in 3 one-hour sessions per treatment with short rest periods between the sessions. The pulsatile delivery mimics a normal "burst" secretion of insulin every 6 minutes. This facilitates a return to "normal" carbohydrate metabolism by the liver and all cells in the body. The return to normal carbohydrate metabolism

generates profound end organ cellular restoration with return of function in underperforming organs⁽⁷⁾.

The treatment is repeated weekly after 2 back to back sessions to initiate the therapy. After metabolism shifts from free fatty acids and lipids to carbohydrates (after approximately 12 weeks), therapy can be extended to every 2 weeks. Further extension to every 3 or even 4 weeks can often be achieved after another 12 weeks of biweekly therapy. The treatment schedule is adjusted for the individual patient based on ability to maintain normal carbohydrate metabolism. Elliott, J et al⁽⁷⁾ reported on the physiologic basis for Microburst Insulin Infusion and the unprecedented results in reversing painful diabetic neuropathy.

We present a series of five diabetic patients with ulceration and tissue necrosis with six large

lower limb wounds. Each ulceration and tissue necrosis had not responded to conventional wound therapy alone. Each of these patients was started on Microburst Insulin Infusion by their provider. In patients with non-healing diabetic ulcers, a more intensive regimen of Microburst Insulin Infusion therapy is often prescribed (2-5 days per week for non-healing wounds).

Case 1 - 67-year-old male with Type 1 Diabetes Mellitus referred to Diabetic Innovations in Arizona for Microburst Insulin Infusion Therapy due to necrotic ulceration of left big toe non-healing after 5 months of conventional therapy. The patient received 19 Microburst Insulin Infusion treatments. *Figures 1 and 2* show the lesion before and after Microburst Insulin Infusion Therapy.



Figure 1 Before Treatment



Figure 2 After Treatment

Case 2 – 60-year-old male with Type II Diabetes Mellitus. This patient developed 4 abscess sites on the right foot. Hospital admission occurred with intravenous antibiotics, multiple incision and drainage procedures were required. There was no evidence of Osteomyelitis. After discharge, hyperbaric oxygen therapy for 4 months with standard wound care resulted in non-healing

lesions. Figure 3 illustrates the largest wound, measuring a volume of 228.6 cm³. Tendon, ligament and muscle are exposed. The patient refused amputation. Microburst Insulin Infusion Therapy was initiated and the patient discontinued hyperbaric oxygen therapy. After 20 treatments, the wounds were considered healed. See figure 4.



Figure 3 Before Treatment



Figure 4 After Treatment

Case 3 – A 65-year-old female with Type II Diabetes Mellitus. She developed peripheral vascular disease with recurrent ischemia of her

left leg which required a femoral popliteal graft bypass. Recurrent ischemia and gangrenous ulceration to that same wound resulted in an

amputation of the left foot second toe. She was referred for Microburst Insulin Infusion Therapy when an ulcer developed on her left great toe. In

Figures 5 and 6, the lesion is shown before Microburst Insulin Infusion and *figures 7 and 8* after 30 treatments, the wound was healed.



Figure 5 Bottom of Foot Before Treatment



Figure 6 Top of Foot Before Treatment



Figure 7 Bottom of Foot After Treatment



Figure 8 Top of Foot After Treatment

Case 4 – A 56-year-old male with Type II Diabetes Mellitus presented with a right foot lesion involving the second and third toes. Amputation was performed on one of those toes. The tissue was not healing after the amputation

and he was referred for Microburst Insulin Infusion. *Figures 9 and 10* illustrates the condition of the foot post amputation and after 38 treatments.



Figure 9 Before Treatment



Figure 10 Before Treatment

Case 5 – A 77-year-old female with Type II Diabetes Mellitus. She was referred for Microburst Insulin Infusion Treatment after multiple wound care therapies and graft placements had failed. There was a non-healing

ulcer of the right great toe. *Figure 11* illustrates the toe prior to Microburst Insulin Infusion Therapy and after 19 treatments, the lesion in *figure 12* has healed without amputation.



Figure 11 Before Treatment



Figure 12 After Treatment

A summary of these 5 patients with 6 non-healing wounds is presented in Table 1. The performance of Microburst Insulin Infusion is presented in comparison to the data from Zimny, et al⁽¹⁾. Microburst Insulin Infusion therapy was successful in promoting healing in 6/6 (100%) lesions including the one colossal lesion in Case

2. This compares more than favorably to Zimny's (2002) report with 5/8 (62.5%) success rate. In addition to the superior wound healing demonstrated by Microburst Insulin Infusion, there was a very significant decrease in the time required to achieve wound healing by 49 days (7 weeks).

Table 1

Case Study #	Pre-MII Wound Area (CM ²)	Total # of MII Tx	Frequency of Tx per week	Time to Healing (Days)	Healed (Y/N)
1	1	19	1X	180	Y
2	228.6	20	2X	102	Y
3	3 rd Toe: 1 Great Toe: 12	30	5X	36	Y/Y
4	6.4	38	5X	32	Y
5	18	19	2X	71	Y
Literature Comparison ¹	6.12	NA	2x	133	5Y/3N

Discussion

Diabetes Mellitus is a growing menace to society. The disease touches us in so many ways. Both type I and type II diabetes change the lives of the patient, their family and has a staggering cost to the healthcare system. Diabetic foot ulcers increase the risk of premature death, stroke and heart disease.⁽⁸⁾ The International Best Practice Guidelines for wound management in diabetic foot ulcers documents that “foot complications account for 20% of the total National Health Service spending on diabetes care, which equates to around 650 million pounds per year⁽⁹⁾.” Worldwide, every 30 seconds a limb is lost due to diabetes and nearly 2 million people in the United States are living with limb loss⁽¹⁰⁾.

Microburst Insulin Infusion is an adjuvant therapy for patients with significant, presumed permanent, morbidities of their disease. These morbidities include: nephropathy, cardiomyopathy, retinopathy, vascular dementia, hypertension, non-healing wounds, fibromyalgia, etc. Microburst Insulin Infusion results in improvement (or even resolution) of these morbidities. Microburst Insulin Infusion mimics normal pancreatic release of insulin in microbursts every 6 minutes. It facilitates normal liver processing of glucose with a resultant restoration of proper carbohydrate utilization for production of adenosine triphosphate in all cells⁽⁷⁾. The mechanism of action for Microburst

Insulin Infusion in assisting wound healing in non-healing diabetic foot ulcers is not entirely clear. It may involve improved cellular metabolism, decreased inflammation and increased levels of nitric oxide that enhance peripheral vascular supply and tissue healing.

Conclusion

The addition of Microburst Insulin Infusion Therapy resulted in a shortening of the time to healing by 49 days (7 weeks) for patients with poor response to conventional wound care. This is a 37% reduction in the time to heal thus reducing the risk of infection and additional healthcare costs. There were no treatment failures in this small series. A prospective study is contemplated to assess possible reduction in limb amputations in patients with diabetic foot ulcers receiving Microburst Insulin Infusion Treatment.

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