

Efficacy and Safety of a Novel Super-Oxidized Solution in the Management of Wide Post-Chirurgical Lesion in the Infected Diabetic Foot

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Introduction:

- The management of acute infected lesions of the diabetic foot is probably the most complex clinical problem in this pathology.
- Drainage and aggressive surgical debridement, combined with adequate systemic antibiotic treatment, are the cornerstones of therapy, especially in cases involving deep structures, which frequently lead to wide open lesions that can have a difficult healing.
- Topical antiseptics are widely used in clinical practice to prevent recurrence of infection, especially in post-surgical lesions that are left to heal by secondary intent.

AIM OF THE STUDY

To evaluate the Efficacy and Safety of a novel superoxidized solution (Dermacyn® Wound Care [DWC]) for the treatment of wide post-surgical infected ulcers of the diabetic foot.

Materials and Methods:

- DWC is a solution made from electrolysis of water and sodium chloride to generate reactive species of chlorine and oxygen. It is pH-neutral.
- DWC was compared with our standard medication for the management of this kind of wounds (50% diluted povidone iodine).
- All patients with diabetes mellitus who underwent surgical debridement or drainage for a diabetic foot infection in our department between June and December 2004 were consecutively screened for entering the study.

IN-/EXCLUSION CRITERIA

- *Inclusion Criteria:* DM type I or II; Postsurgical lesion area > 5 cm²; 3B Texas University grading scale; TcPO₂ > 50 mmHg distal to the ankle
- *Exclusion Criteria:* Bilateral ulceration; Active or chronic Charcot's foot; Peripheral arterial disease not amenable to revascularization; Life expectancy less than 1 year

Patient Characteristics	Group A DWC	Group B PI
Number (DM1/DM2)	18(4/14)	15(3/12)
Age (yrs)	62.4±9.7	63.7±12.2
Duration of Diabetes (yrs)	21.7±10.3	19.8±9.1
Hb1Ac (%)	8.2±1.1	8.8±1.9
Area of the lesion (cm ²)	25.8±10.4	20.2±12.3
Duration of ulceration (days)	95.7±52.4	78.3±65.8

Methods:

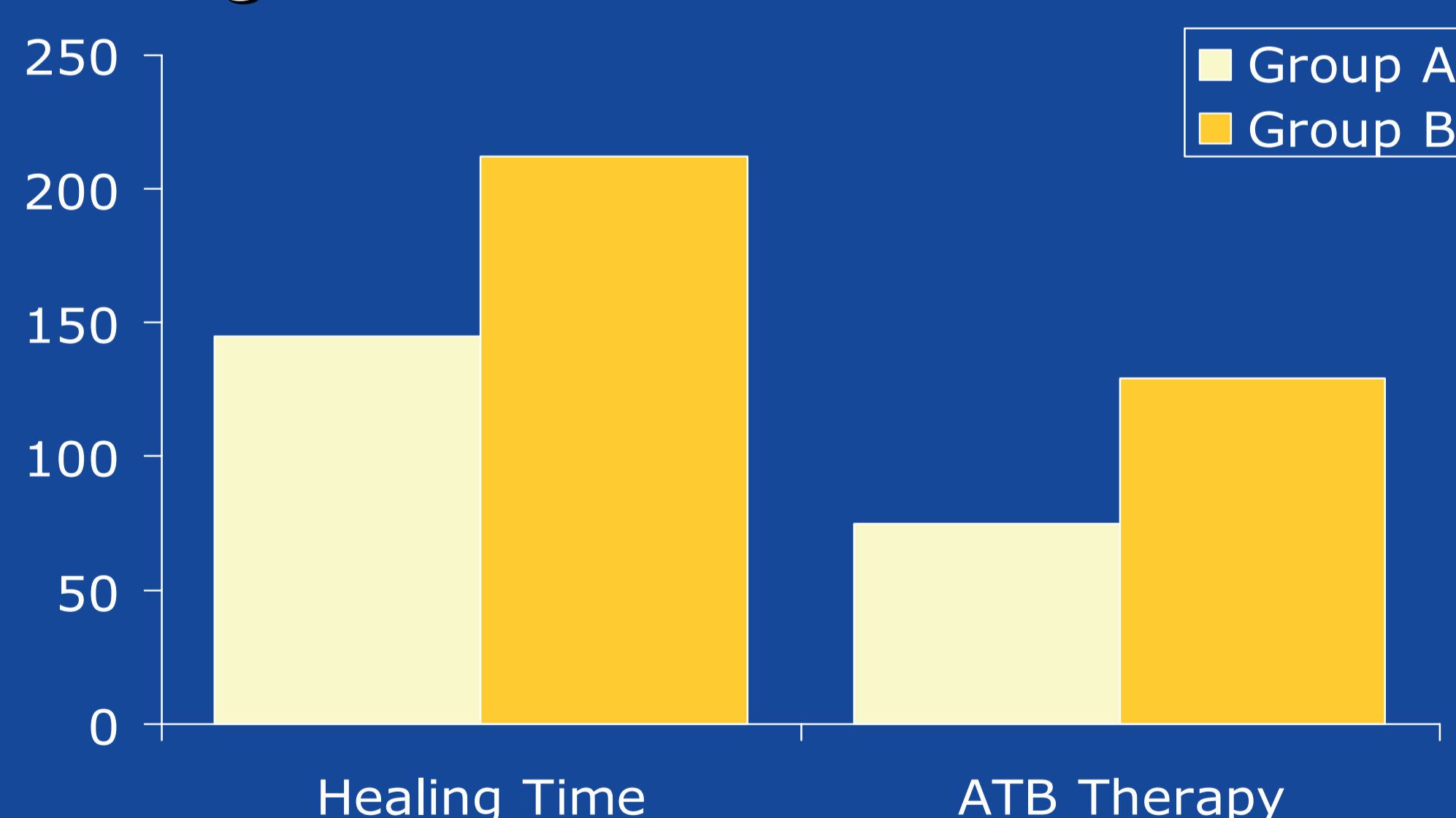
- After surgical debridement or drainage the patients' lesions were allowed to close with secondary intent.
- Patients received systemic antibiotic therapy based on microbiological investigation
- A group (GROUP A, n=18) of patients was locally treated with DWC, and the other one (GROUP B, n=15) was treated with diluted Povidone Iodine.



The dressing of lesions was a sterile gauze soaked with DWC for Group A, and Povidone Iodine for Group B, which was renewed daily via a catheter to keep the gauze saturated with the solution

RESULTS

Healing Time/Duration of Antibiotic Therapy



RESULTS	Group A DWC	Group B PI	p
Patients (n)	18	15	
Healing Time (days)	144 ± 39	212 ± 67	0.00361
% ulcers healed at 6 months	87.5	51.4	0.00827
Duration of antibiotic therapy (days)	74 ± 32	129 ± 54	0.01373
Surgical debridement procedures (n)	6	16	0.00121

CONCLUSION

Dermacyn® Wound Care is more effective than povidone iodine in treating wide postsurgical infected wounds of the diabetic foot and promoting healing. However, there are no differences in safety between the two treatments.

References:

- Caputo GM, Cavangh PR, Ulbrecht JS, Gibbons GW, Karchmer AW. Assessment and management of foot disease in patients with diabetes. *N Engl J Med* 1994;331:8
- Lipsky BA, The international Consensus Working Group on Diagnosing and treating The Infected Diabetic Foot: a report from the internationale consensus on diagnosing and treating the infected diabetic foot. *Diabetes Metab Res Rev* 2004; 20 (suppl 1). S68-77