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Topical oxygen therapy for chronic wounds: a report on the potential of NATROX™ a new device for delivering enriched oxygen to chronic wounds

Abstract

Topical oxygen therapy has excited wound healers for some considerable time. This paper presents the potential of NATROX™ topical oxygen used to treat a short series of patients with venous ulcers. The uncontrolled study permits the observations that the NATROX™ device is safe and has promise towards the treatment of chronic lower extremity wounds.

Keywords: topical oxygen therapy, chronic wounds

Introduction

Some 25 years back in pursuit of the pathogenesis of venous ulcers the author measured transcutaneous oxygen ($TCPO_2$) levels of 20 mm Hg and less around venous ulcers though these tissues had pulsatile dermal blood supply.[1] How the tissues could survive in such low oxygen levels? It is now understood that the microcirculation in ulcerated tissue is impaired[2] and that peri capillary cuffs exist trapping molecules including growth factors[3] which cause venous ulceration. Better understanding of the $TcPO_2$ technique now exists and taken together, it seems reasonable to state that some indolent venous ulcers may have less than necessary oxygen ***available*** for healing, and topical oxygen therapy (TOT) may offer a solution.

In a recent review, Gordillo and Sen explained the mechanistic reasons behind TOT and proposed how to select patients for this treatment modality.[4] In the same paper, the authors described an experiment that demonstrated that topically delivered oxygen could diffuse through superficial dermal tissues in wounds. Oxygen has critical roles in the production of collagen, in angiogenesis through the production of vascular endothelial growth factor and in the scavenging process that is essential before repair is initiated. All this knowledge has accrued from acute and chronic experimental wounds. Does this translate to chronic wounds in the human?

Figure 1. NATROX™ device, shown here to be worn around the Waist. Pure (96.2%) humidified oxygen is produced at ~15ml/hr.

This paper describes a new TOT device Inotec's NATROX™ and preliminary clinical experiments to demonstrate its safety and potential.

Safety and efficacy study

A first safety study was done by the authors group at Southampton University Hospital Trust with Ethics Approval from the local Ethics Committee NHS Trust No RHM MED0818. This study on 4 patients with evidence of venous disease and chronic wounds lasted 6 weeks on each case. The study was discontinued on 2 patients. Patient 1 expressed a wish to discontinue; the other became ill for unrelated reasons. Overall the study showed the device to be safe.

A second study was done. This was an uncontrolled observational study on 10 patients over 6 weeks and carried out by a specialist group of Tissue Viability Nurses at Tissue Viability Consultancy Services Ltd (TVCS) in Eastbourne. The aims of this study were:

- To examine the safety of the device and;
- To record changes in wound area over the 6 weeks the device was used.

Patients (N = 10, 8F, 2M, age range 51-84 years, mean age 69.5 years) with venous ulcers but without any other significant comorbidity were included with prior informed written consent.

Swabs were done on all 3 visits for all patients and sent for semi quan-

Figure 2. The NATROX™ system: Oxygen generator and the Island Oxygen Delivery Pad. Within 5 hours of fitting Oxygen concentration in the headspace above the Wound increases by 20%.

CASE 2			
PATIENT'S DETAILS	S04 MG 74 years, female with a venous ulcer on a left medial malleolus. Wound duration was 2. 5 years with the current episode of care 9 months. Ulcer failed to respond to various treatments. ABPI 0.97. Treatment used was NATROX™ 25 Low Flow oxygen Device.		
SWAB RESULTS	Start	2 Weeks	6 Weeks
	+++ mixed enteric flora ++ Staphylococcusaureus	+++ Coliform spp. +++ beta-haemolytic Streptococcus of Lancefield Group B isolated	+++ Coliform spp.
SIZE OF THE WOUND	16.24	10.18	5.94
PATIENT'S SATISFACTION	Comfort	Convenience	Overall Assessment
	5	3	5
CASE DESCRIPTION	This patient was selected to use the low-flow oxygen device on account of a known hypersensitivity and tendency to get skin maceration. High levels of fluid produced during treatment with NATROX™ . Patient was advised to switch this device off at night to lower amount of exudates which was helpful. Wound area decreased during the study.		

CASE 3			
PATIENT'S DETAILS	S05 RK 51 y.o. male with recurring venous leg ulcer on R) lateral gaiter skin. ABPI 1.15, treatment used was NATROX™ 30		
SWAB RESULTS	Start	2 Weeks	6 Weeks
	+++ Staphylococcusaureus	+++ mixed skin flora	+++ mixed skin flora
SIZE OF THE WOUND	24.48	14.53	6.12
PATIENT'S SATISFACTION	Comfort	Convenience	Overall Assessment
	No answer given	No answer given	No answer given
CASE DESCRIPTION	This patient was a chef. His work required him to stand for long periods in a stressful environment and he was a smoker. Ulcer pain significantly decreased from 8 to 2 during the study. However it was difficult for the patient to wear the device while continuing to work.		

CASE 4			
PATIENT'S DETAILS	S06 EL 82 year old lady with a non-healing venous leg ulcer on the right medial mid-gaiter region. Patient had a history of varicose veins and silver allergy, ABPI 0.97 and treatment used was NATROX™ 36.		
SWAB RESULTS	Start	2 Weeks	6 Weeks
	+++ Staphylococcusaureus +++ Coliform spp.	+++ Coliform spp.	Not Applicable (healed)
SIZE OF THE WOUND	36	13.22	0
PATIENT'S SATISFACTION	Comfort	Convenience	Overall Assessment
	4	3	5
CASE DESCRIPTION	When started using NATROX™ at first her surrounding skin became excoriated and macerated with charac-teristic red demarcation matching the TOT dressing. A zinc impregnated bandage was used to lower the risk of further skin damage with satisfactory results.		

References

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Conflict of interest: Raj Mani has received industry support towards clinical trials, honoraria for presenting lectures as well as unrestricted educational grants.

Disclaimer - The photos in this report have been updated to reflect the NATROX™ Oxygen Generator and Delivery System.