Original Article

A Clinical Study to Evaluate Autofluorescence Imaging of Diabetic Foot Ulcers Using a Novel Artificial Intelligence Enabled Noninvasive Device

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Vijay Viswanathan, MD, PhD, FICP, FRCP(London), FRCP(Glasgow)[1], Senthil Govindan, MBBS, MS(General Surgery), MCH(Plastic Surgery)[1], Bamila Selvaraj, MPT(Neurology), MIAP, Dip. in Podiatry[1], Secunda Rupert, MD[2], and Raghul Kumar, M Sc[3]

Abstract

Diabetic foot ulcers, with worldwide prevalence ranging from 12%-25%, are an important cause of nontraumatic lower limb amputation. Evidence-based assessment of early infection can help the clinician provide the right first line treatment thus helping improve the wound closure rate. Illuminate®, a novel point of care device working on multispectral autofluorescence imaging, helps in the rapid identification and classification of bacteria. This study was aimed to evaluate the diagnostic accuracy of the device in detecting bacterial gram type against standard culture methods. A total of 178 patients from a tertiary care center for diabetes was recruited and 203 tissue samples were obtained from the wound base by the plastic surgeon. The device was handled by the trained investigator to take wound images. The tissue samples were taken from the color-coded infected region as indicated by the device's Artificial Intelligence algorithm and sent for microbial assessment. The results were compared against the Gram type inferred by the device and the device was found to have an accuracy of 89.54%, a positive predictive value of 86.27% for detecting Gram-positive bacteria, 80.77% for Gram-negative bacteria, and 91.67% for no infection. The negative predictive value corresponded to 87.25% for Gram-positive, 92% for Gram-negative, and 96.12% for no infection. The Results exhibited the accuracy of this novel autofluorescence device in identifying and classifying the gram type of bacteria and its potential in significantly aiding clinicians towards early infection assessment and treatment.

Keywords

diabetic foot ulcers, illuminate®, gram-positive bacteria, gram-negative bacteria, multispectral imaging, autofluorescence, artificial intelligence

Introduction

The International Diabetes Federation estimates that the expected prevalence of diabetes mellitus will rise to more than 570 million in 2030.[1] Diabetic foot ulcers (DFU), and diabetic foot infections are major contributors of worldwide morbidity and mortality as they lead to limb amputation in 12%-25% of individuals with diabetes.[2] DFU initially begins with peripheral neuropathy and finally lead to ulcerations. Secondary infections leads to chronically infected wounds over a period of time.[3] Prompt diagnosis of bacteria in these wounds and timely treatment help speed up the wound healing process. However, it is clinically difficult to diagnose the causative pathogens causing

[1]MV Hospital for Diabetes and Prof M Viswanathan Diabetes Research Centre, Chennai, Tamil Nadu
[2]Stem Cell Research Centre, Government Stanley Medical College & Hospital, Chennai, Tamil Nadu
[3]Adiuvo Diagnostics Private Limited, Chennai, Tamil Nadu

Corresponding Author:
Vijay Viswanathan, M.V. Hospital for Diabetes and Prof. M. Viswanathan Diabetes Research Centre (WHO Collaborating Centre for Research, Education and Training in Diabetes) (IDF centre for Excellence in Diabetes care), No. 4, West Madha Church Street, Royapuram, Chennai, Tamil Nadu, India.
Email: drvijay@mvdiabetes.com