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Spectroscopic Analysis Of Diabetic Foot Ulcer Patients.

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Abstract:
An infected diabetic foot ulcer is the common cause of morbidity in diabetic patients leading to the complications like gangrene and amputation. Illuminate, A Device that helps in the identification and type of bacteria (Gram positive or negative) and In point of care settings by Multispectral autofluorescence imaging is considered simple, affordable,and non-time consuming and initiates appropriate antibiotics without any delay. The device excites the bacterial organisms with ultraviolet and blue light which in turn have characteristic emission of fluorescence from the organism which has been captured by the device, records the spectral signature, An Inbuilt image is processed and the artificial intelligence algorithm in the machine detects the native fluorescence emitted by the bacteria according to their Gram type.
This study was done in a tertiary care hospital With a total of 15 number of Patients, where we evaluated both spectroscopy and standard culture sensitivity test and found that the illuminate device was able to detect the microorganism with 92.9%Sensitivity and 50 % Specificity to the culture sensitivity test and with the accuracy of 71.15%.This device has the potential to help clinicians to identify wound with significant bacteria which maximizes the treatment for the infected diabetic foot ulcer with early start of appropriate antibiotics.

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I. Introduction:

Antimicrobial resistance has the same negative effects on healthcare as global warming[1]. The most huge challenge to overcoming antimicrobial resistance is the creation of a point-of-care (POC) diagnostic test to identify the presence of a bacterial infection that is affordable, precise, quick, and simple to use. This test would allow clinicians to administer the appropriate antibiotics at the appropriate time. When bacteria are quickly found in wounds, blood, or bodily excretions, the specific pathogen is treated. Currently, a tissue swab from the ulcer is used to do a culture and sensitivity test in order to detect wound infection.

A microbiology laboratory is needed for this, and it takes roughly 48-72 hours to determine the type of bacteria. Although there are numerous phenotypic and molecular methods for detecting microbes, they are laborintensive, reagent-intensive, and demand for specialized expertise, making them unsuitable for quick screening. Recent innovations have been found to be sensitive and successful for the quick screening of bacterial infections and classification [3], taking advantage of the fluorescence of bacterial cell molecules. [3].

II. Aim:

To study the effectiveness of this handheld device (Illuminate) to determine the presence of infection, classify the gram type of infecting bacteria, and to compare the results with those obtained by the standard tissue culture method.

III. Methodology:

Study design: a prospective Observational study **Sampling method:** Simple random sampling**.**

Sampling size: 15

Study tool: Illuminate imaging device, swab culture results

Inclusion criteria: Type2 diabetic patients with diabetic foot ulcer.

Data analysis: Data collected will be entered in MS Excel and will be analyzed using Statistical package for social sciences (SPSS) software**.**

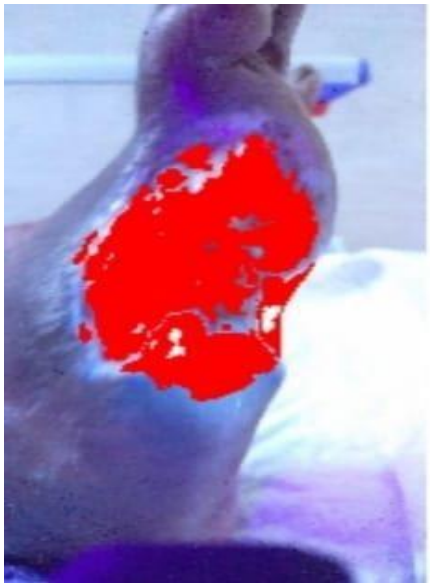
Illuminate Device:

A start up primarily based in India has developed and patented (IN Patent–323,440) a unique handheld device, (Illuminate®), which makes use of the native fluorescence of bacteria for its detection [4] (Fig. 1). Each bacterium has characteristic specific fluorescence when excited with an extraordinary wavelength[5, 6]. The device was based on multispectral imaging combined with state of an art AI engine for spatial mapping and type of bacteria. The device captures the spectral signature markers of the microorganism reasons for infection, to locate and assess the bacterial gram type. The device leverages the Autofluorescence property exhibited through bacterium [such as Nicotinamide adenine dinucleotide hydrogen (NADH), flavins] And infectious markers [Pyoverdine, Porphyrin] present. In microorganisms and fungi [6] Use of such handheld devices Has been carried out very effectively in diagnosing skin and smooth tissue. Contamination—a bacterial and fungal infection.

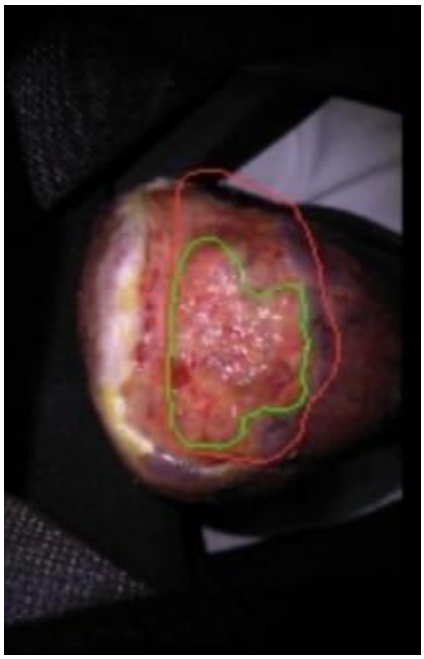
All patients attending plastic surgery OPD , admitted in ward with diabetic foot ulcers included in the study. After clinical examination and thorough wound wash, wound swab for culture and sensitivity taken from the clinically suspecious area. After this, the ulcer was imaged by this device either in a dark room or under a black hood.The Illuminate device captures images of the ulcer, in a dark room at a distance of 7 to 10 cm away from the wound. The Gram type displayed immediately by the device was recorded in a prepared proforma. After 48 hrs, culture reports were compared with the device report (Gram type).

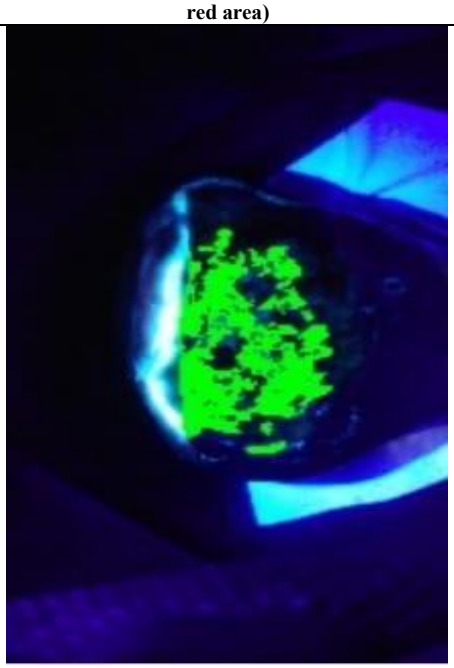
Figs. 2 show the images taken by the device and clearly indicating the site of infection, the Gram type of bacteria infecting the wound and size of the ulcer.The device finds the presence or absence of bacteria in the ulcer, maps the exact location of the infection, and classifies the Gram type of bacteria within 2 minutes.

Fig 2 Pictures captured in an illuminate device



1)example of gram-positive bacteriainfected ulcer (showing red area)





2) example of gram-negative bacteria-infected ulcer (showing green area)

IV. Results:

Out of 15 patients 10 were male and 5 were female. Diabetic foot ulcer gram-type results obtained by the illuminate device are compared with the swab culture study from the microbiology department. The device displayed a red and green color covered over the surface of the ulcer indicating Gram-positive and Gram-negative bacteria respectively.

From our study, Results of the Illuminate device showed 46.7% of grampositive bacteria, 40% of gram-negative bacteria in the spectral study and culture method showed about 46.7% of gram-positive and gram Negative bacteria in the culture study. No growth seen in 13.3% of the spectral study and 6.7% in culture study.

As for as the type of organisms concerned, our study shows about 33.3% of staphylococcus aureus-infected diabetic foot ulcers followed by 26.7% of E.coli infected diabetic ulcers. The sensitivity of the illuminate device for detecting the growth in infected ulcers is 92.9%. Our study showed a sensitivity of 85.71%, and a specificity of 83.33%for identifying the gram type of bacteria in infected diabetic foot ulcer with the spectroscopy device.

The Illuminate spectroscopy device has shown a positive predictive value of 85.71%for identifying the gram type of the Bacterium with an accuracy of 84.62%.Cohen's Kappa (K) to set on the agreement between the culture method and the illuminate device is K= 0.659 showing substantial agreement between the spectroscopy study and culture study. The illuminate device shows mostly the correct gram type of organism in the infected diabetic foot ulcer.Cramer's V is used to interpret the values of the association between the spectral and culture study for diagnosing the bacteria which is 0.688. It shows that the illuminate device has a very strong interpretation of association with the standard culture method for diagnosing the microorganism.

TABLE 1,2: Test results of culture vs Spectroscopy

Screening test culture/spectroscopy		**Growth according to culture report**		
		Growth seen	**No growth seen**	**Total**
Growth according to spectroscopy	**Growth seen**	12(TP)	1(FP)	13
	No growth	1(FN)	1(TN)	2
	Total	13	1	15

Sensitivity of spectroscopy	92.3%
Specificity of spectroscopy	50%
Positive predictive value	92.3%
Negative predictive value	50%
Accuracy	**71.15%**

Table 3: Comparison of detection of Gram-negative, Gram-positive, and no growth by spectroscopy and culture method.

Culture/spectroscopy		**Growth according to culture**		
		Gram-positive	**Gram-negative**	**No growth**
Growth according to spectroscopy	**Gram-positive**	6	1	0
	Gram-negative	1	5	0
	No growth	0	1	1

Table 4: Sensitivity specificity for spectroscopy method FOR gram type

Sensitivity of Spectroscopy	85.71%
Specificity Spectroscopy/Culture	83.33%
Positive predictive value	85.71%
Negative predictive value	83.33%
Accuracy	84.22%

Table 5: Results of bacteria obtained through the culture method

Culture: organisms	Frequency	Percent
E.coli	4	26.7%
Enterococcus	2	13.3%
Klebsiella	2	13.3%
No growth	1	6.7%
Pseudomonas aeruginosa	1	6.7%
S.aureus	5	33.3%
Total	15	100.0

V. Discussion:

The mechanism of Diabetic foot ulcer is essential for the treatment as well as to prevent the complication related to the ulcer. However, the study of spectroscopy for diabetic foot ulcers is instinctive. So accurate methods and objectives are needed for the Doctors to approach this device and provide the correct antibiotics. Our study showed the sensitivity of detecting gram-negative and gram-positive bacteria is 85.71 %, whereas the study done by Viswanathan et al showed the sensitivity of gram-negative and gram-positive bacteria was 91.3% (3) which was comparable to our study in detecting the pathogen.

Our study showed the accuracy of bacterial growth was 71.15%. The study conducted by Parkhe with the accuracy of finding bacterial growth was 92.3% (6) which was similar to our study. Our study showed specificity for detecting Gram-negative organisms is 83.3%. where the study conducted by Vijay (6) showed a specificity of 93.2% which is similar to our study, because the study has been conducted on varicose ulcers only which showed increased specificity due to soft tissue involvement where in our study, where involves the wound exposing the bones, tendons where the fluorescent image shows false gram negative fluorescent image.

Our study shows the most common organism involved here is E.coli which is about 26.7%.The study conducted by Bansal(7) showed that infection E.coli is found in about 18%. Shows that E.coli is the second common organism involving in the infected diabetic foot ulcer(9)

Our study showed that illuminate devices finds the Gram type of Organism involved in diabetic foot ulcer Instantaneously in the clinical setting so it can also be used in operation theatres for detecting the Organism in the Surgical wound area which would help in early administration of antibiotics prevent the complication (8). It can also be used for detecting the microorganism in any instruments in the clinical setup and operation theatre.

The device also measures the extent of the ulcer so that progress of wound healing can be observed in the follow-up of patients. The test report is given instantly, and the data's are stored and transferred via a USB drive or via the cloud, connecting to hospital records. The feasibility of the device is good as it can be physically carried everywhere.

VI. Conclusion:

Among the many recently discovered methods for detecting bacterial infections, those that rely on the bacteria's fluorescent properties can be easy, affordable, and quick. This recently created tool is a perfect illustration of the same which helps in early start of appropriate antibiotics.

Currently, this device just displays the Gram type of bacteria, not the species. The AI in the gadget will eventually be able to distinguish between the gram type of infectious bacteria on future studies. The instrument's accuracy, which is about 71.15%, is above average, but the accuracy can be improved with larger population study.

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