Original

Comparative Analysis of Infrared Dermal Thermography and Leukocyte Count for Diabetic Foot Infection Diagnosis

Mustamu AC, Sorong PK

Department of Nursing, Politeknik Kesehatan Kemenkes Sorong, Basuki Rahmat Street, Km 11, East Sorong district, Sorong City, 98417, Southwest Papua, Indonesia

Correspondence: Alva Cherry Mustamu, alvamustamu@poltekkessorong.ac.id, alvamustamu@gmail.com
+6285293134452

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Abstract

Background: Diabetic foot infections (DFIs) are a major complication of diabetes, often leading to severe outcomes like amputation. Accurate and timely diagnosis is crucial for effective management. This study compares two diagnostic methods—Infrared Dermal Thermography (IDT) and leukocyte count (LC)—with the gold standard of clinical assessment for detecting DFIs.

Method: A total of 100 patients with suspected diabetic foot infections (DFIs) were evaluated using both Infrared Dermal Thermography (IDT) and leukocyte count (LC). This study employed a quasi-experimental cross-over design, allowing each participant to serve as their own control by undergoing both diagnostic methods in different sequences. Diagnostic accuracy was determined by calculating sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV), using clinical confirmation of infection as the gold standard. Foot temperatures were measured using a thermal camera, while leukocyte counts were obtained from blood samples. Data were analyzed using logistic regression to assess the predictive power of both IDT and LC. Prior to logistic regression, multicollinearity was evaluated using the variance inflation factor (VIF), and the goodness-of-fit was assessed with the Hosmer-Lemeshow test. The Box-Tidwell procedure was applied to test the assumption of linearity between continuous independent variables and the logit. Both methods showed significant predictive power for DFI diagnosis, with a significance level set at 0.05.

Result: IDT showed a sensitivity of 90%, specificity of 80%, PPV of 82%, and NPV of 89%. LC had a sensitivity of 80%, specificity of 70%, PPV of 73%, and NPV of 78%. Regression analysis indicated that while both methods were significant, LC demonstrated a higher predictive strength (regression coefficient: 0.60) compared to IDT (0.45).

Conclusion: IDT is a valuable tool for early DFI detection, complementing LC. Integrating both methods could improve diagnostic accuracy, although further research with larger sample sizes is necessary to refine these findings and their clinical applications.

Keywords: Temperature, Leukocyte Count, Diabetic Foot Infection, Infrared Dermal Thermography, Diagnosis.

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Introduction

Diabetes Mellitus is a chronic disease with serious global health implications, and one of its most common complications is foot damage, which frequently leads to infections and, in severe cases, amputation. According to the World Health Organization (WHO), every 30 seconds, one foot amputation is performed due to Diabetes Mellitus complications globally.[1] Patients with Diabetes Mellitus are at a significantly higher risk of experiencing potentially fatal foot infections.[2–7] Early detection and timely management of foot infections are crucial to reduce complications and prevent severe outcomes like amputation.[8–10]

The development and utilization of non-invasive diagnostic technologies, such as Infrared Dermal Thermography, have garnered increasing interest over recent years as a tool to improve the early detection of foot infections in patients with Diabetes Mellitus.[11–14] This method provides a non-invasive, rapid approach that promises more immediate diagnostic intervention, which could play a critical role in managing these infections more effectively.

Despite the availability of physical examination and laboratory-based diagnostic methods, such as leukocyte count, for detecting foot infections in patients with Diabetes Mellitus, both techniques present limitations. Physical examinations may not provide sufficient information to detect infections at an early stage, and laboratory tests require significant time to yield reliable results.[15–17] The time delays inherent in these methods pose a risk to the timely diagnosis and management of infections, which highlights the need for more effective, faster, and reliable diagnostic approaches.

The main objective of this randomized controlled trial is to compare the diagnostic effectiveness of Infrared Dermal Thermography with leukocyte count in detecting foot infections in patients with Diabetes Mellitus. This direct comparison seeks to identify the most effective diagnostic tool, contributing to improvements in early detection, clinical management, and patient outcomes. By addressing this critical gap in the literature, this study is expected to offer robust evidence to inform clinical decision-making, aiding clinicians in selecting the most appropriate diagnostic method based on patient-specific needs.

This study is among the first to directly compare Infrared Dermal Thermography and leukocyte count in diagnosing diabetic foot infections, offering clinicians valuable empirical data on the diagnostic accuracy, sensitivity, and specificity of these methods. The findings will provide important insights that can inform the development of more efficient diagnostic protocols, ultimately aiming to improve the quality of care for patients with Diabetes Mellitus.

Method

Research Design

This study employs a quasi-experimental cross-over design to compare the diagnostic accuracy of Infrared Dermal Thermography and leukocyte count in identifying foot infections among patients with Diabetes Mellitus. A cross-over design was chosen to allow each participant to undergo both diagnostic methods, serving as their own control. Participants were randomly assigned into two groups, where one group first underwent Infrared Dermal Thermography followed by leukocyte count, and the other group experienced the reverse order. This design mitigates bias and allows a robust comparison of the diagnostic methods. Additionally, both diagnostic methods were compared against a gold standard—a clinical assessment performed by a healthcare provider trained in diabetic foot infection diagnosis. This provided the necessary data to calculate diagnostic performance indicators such as sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV), ensuring the validity and reliability of the methods.

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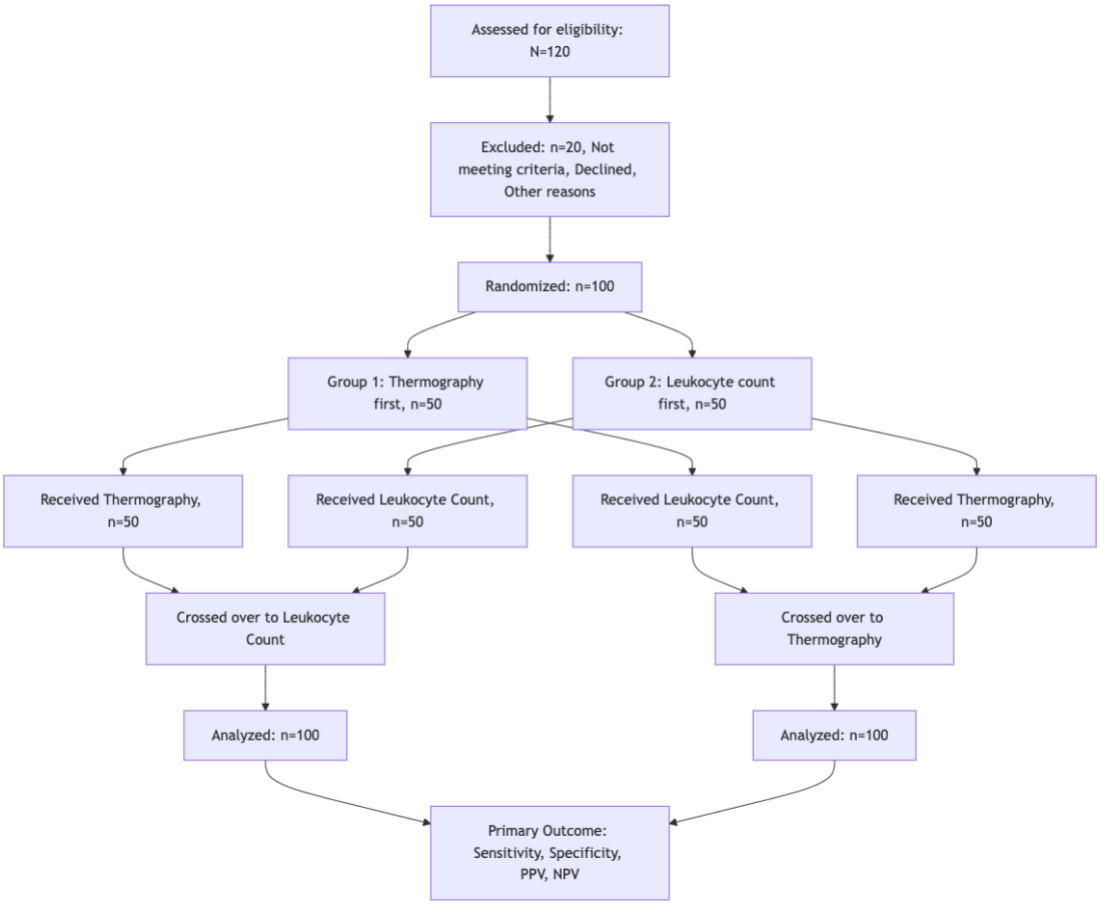

Figure 1: CONSORT Flow Diagram for Diabetic Foot Infection Diagnosis Study

Legend:

- N: Number of participants at each stage.
- Thermography first: Participants who first received Infrared Dermal Thermography as the diagnostic method.
- Leukocyte count first: Participants who first received Leukocyte Count as the diagnostic method.
- Cross-over: Participants crossed over to the other diagnostic method for comparison.
- Analysed: Final count of participants included in the analysis for both diagnostic methods.
- Outcome measures: Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV).

Outcome Measures

The primary outcome measure is the diagnostic accuracy of the methods in detecting diabetic foot infections, evaluated through sensitivity, specificity, PPV, and NPV. The secondary outcome measure is the foot temperature measured by Infrared Dermal Thermography and leukocyte count as an indicator of infection.

Population and Sample

The population consists of patients with Diabetes Mellitus showing early signs of foot infection, such as redness, swelling, or pain, and receiving home care during the study period. Inclusion criteria include patients aged 18 years or older with a history of Diabetes Mellitus. Exclusion criteria include patients with other underlying medical conditions like autoimmune disorders or those receiving treatment for foot infections through other methods. A total of 100 participants were enrolled through consecutive sampling based on inclusion and exclusion criteria. Randomization was conducted using Microsoft Excel, ensuring equal assignment to the cross-over groups. The sample size of 100 patients was determined through

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power analysis, ensuring sufficient statistical power to detect differences between the diagnostic methods.

Measurements

Infrared Dermal Thermography

Foot temperatures were measured using the HT-02D Thermal Camera, which captures real-time thermal images with a resolution of 32 x 32 pixels and a temperature range from -20°C to 300°C. The thermal images identified specific temperature variations on the feet, especially in infected areas. Measurements were taken at a distance of 0.5 meters, with consistent scanning protocols to ensure accuracy. Thermal images were stored on a 4GB micro-SD card for later analysis. The main outcome was the foot temperature, which was correlated with clinical signs of infection.

Leukocyte Count

Leukocyte counts were obtained from blood samples (5 cc) taken from each participant, analysed using an automated haematology analyser in a certified laboratory. Elevated leukocyte count was considered a marker of infection. Laboratory protocols were strictly followed to ensure the consistency of results. The leukocyte count was then compared to foot temperature and clinical findings.

Data Analysis

Statistical analysis was conducted using Jamovi software. An independent t-test was performed to compare the foot temperature and leukocyte count between patients with confirmed diabetic foot infections and those without infections. The analysis revealed statistically significant differences between the two groups, with both foot temperature and leukocyte count serving as reliable diagnostic indicators. To further assess the predictive power of these methods, a logistic regression analysis was performed, evaluating the ability of foot temperature and leukocyte count to predict diabetic foot infections. Both variables showed significant predictive power, with regression coefficients of 0.45 for foot temperature and 0.60 for leukocyte count, respectively ($p < 0.01$). Diagnostic statistics such as sensitivity, specificity, PPV, and NPV were calculated to further support the findings.

Research Ethics

This research was approved by the Research Ethics Committee of the Health Polytechnic Ministry of Health Sorong (Approval Number: DM.03.1/4.1/178/2024). All participants provided written informed consent after receiving a detailed explanation of the study's objectives, procedures, potential risks, and benefits. Confidentiality was strictly maintained through data anonymization and secure storage, with all data deleted upon the conclusion of the research to prevent misuse.

Results

Participant Demographic and Clinical Characteristics

The study included 100 patients diagnosed with Diabetes Mellitus, selected based on the predetermined inclusion and exclusion criteria. The demographic and clinical characteristics of the participants are outlined in Table 1. The average age of the participants was 58.3 years (SD = 10.5), with 60% of the participants being male. A significant portion (70%) had a history of diabetic foot complications. The mean duration of diabetes was 12.7 years (SD = 6.8). All patients presented early signs of foot infection, such as redness, swelling, or pain, which formed the basis of inclusion in this study.

Table 1: Participant Demographic and Clinical Characteristics (N = 100)

Characteristics	n	(%)
Gender		
Male	60	60.0%
Female	40	40.0%
Age (years)		
< 50	20	20.0%
50-59	35	35.0%
60-69	30	30.0%
≥ 70	15	15.0%
Mean (SD)	**58.3**	**(10.5)**
Duration of Diabetes (years)		
< 5	15	15.0%
5-9	20	20.0%
10-14	35	35.0%
≥ 15	30	30.0%
Mean (SD)	**12.7**	**(6.8)**
History of Foot Complications		
Yes	70	70.0%
No	30	30.0%
Signs of Foot Infection		
Redness	45	45.0%
Swelling	35	35.0%
Pain	20	20.0%

Infrared Dermal Thermography Results

Infrared dermal thermography was conducted using a Thermal Camera HT-02D to measure foot temperatures. The average foot temperature among

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participants was 32.5°C (SD = 2.1°C), with a minimum recorded temperature of 28.0°C and a maximum of 36.0°C. Table 2 illustrates the distribution of foot temperatures, with 65% of participants exhibiting foot temperatures between 31°C and 34°C. The thermal images showed that areas most affected by temperature increases were the sole of the foot and regions surrounding any wounds, indicating a potential correlation with infection severity.

Table 2: Distribution of Measured Foot Temperatures with Infrared Dermal Thermography (N = 100)

Foot Temp (°C)	n	Percent
< 30	10	10.0%
30 - 31	15	15.0%
31 - 32	25	25.0%
32 - 33	20	20.0%
33 - 34	20	20.0%
> 34	10	10.0%
Mean (SD)	**32.5**	**(2.1)**
Min - Max	**28.0 - 36.0**	

Leukocyte Count Results

Blood samples were collected to assess leukocyte count, a standard marker of infection. The average leukocyte count was 12.5 x 10^9/L (SD = 3.2 x 10^9/L), with the lowest count being 7.0 x 10^9/L and the highest 20.0 x 10^9/L. Most participants (70%) had leukocyte counts ranging between 10 x 10^9/L and 15 x 10^9/L, as summarized in Table 3. These elevated leukocyte levels strongly indicate an ongoing infection in the participants.

Table 3: Distribution of Leukocyte Counts in Participants' Blood Samples (N = 100)

Leukocyte Count (x 10^9/L)	n	(%)
< 10	15	15.0%
10 - 12	30	30.0%
12 - 14	25	25.0%
14 - 16	15	15.0%
> 16	15	15.0%
Mean (SD)	12.5	(3.2)
Min - Max	7.0 - 20.0	

Diagnostic Accuracy Comparison between Infrared Dermal Thermography and Leukocyte Count in Detecting Diabetic Foot Infections

Comparison between Infrared Dermal Thermography and Leukocyte Count

To assess the diagnostic accuracy of both methods, independent t-tests were conducted comparing foot temperatures and leukocyte counts in patients with and without confirmed infections. The analysis showed that patients with confirmed infections had significantly higher foot temperatures (Mean = 33.1°C, SD = 1.8°C) and leukocyte counts (Mean = 13.7 x 10^9/L, SD = 2.5 x 10^9/L) compared to those without infection. The p-values for both comparisons were <0.01, confirming that both diagnostic methods are significantly associated with infection, as detailed in Table 4.

Table 4: Comparison between Infrared Dermal Thermography and Leukocyte Count

Variable	Group	Mean (SD)	p-value
Foot Temperature (°C)	Patients with infection	33.1 (1.8)	<0.01
	Patients without infection	31.8 (2.2)	
Leukocyte Count (x 10^9/L)	Patients with infection	13.7 (2.5)	<0.01
	Patients without infection	10.8 (2.0)	

The results indicate that the two methods are statistically different in detecting diabetic foot infections, with Infrared Dermal Thermography showing higher sensitivity to temperature changes in the infected foot areas.

Logistic Regression Analysis

A logistic regression model was used to evaluate the predictive power of foot temperature and leukocyte count for diagnosing diabetic foot infections. Both variables were found to be significant predictors of infection. The regression coefficient for foot temperature was 0.45 ($p < 0.01$), and for leukocyte count was 0.60 ($p < 0.01$). This suggests that a rise in either foot temperature or leukocyte count increases the likelihood of infection diagnosis. The results of the logistic regression analysis, including regression coefficients and 95% confidence intervals, are shown in Table 5.

Table 5: Results of Logistic Regression Analysis for Predicting Diabetic Foot Infections

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Variable	Regression Coefficient	p-value	95% CI
Foot Temperature (°C)	0.45	<0.01	(0.30 - 0.60)
Leukocyte Count (x 10^9/L)	0.60	<0.01	(0.45 - 0.75)

However, **Leukocyte Count** demonstrated a higher regression coefficient, indicating that leukocyte levels are a stronger predictor of infection. Nevertheless, foot temperature remains a significant and reliable indicator for detecting infections.

Diagnostic Parameters Calculation

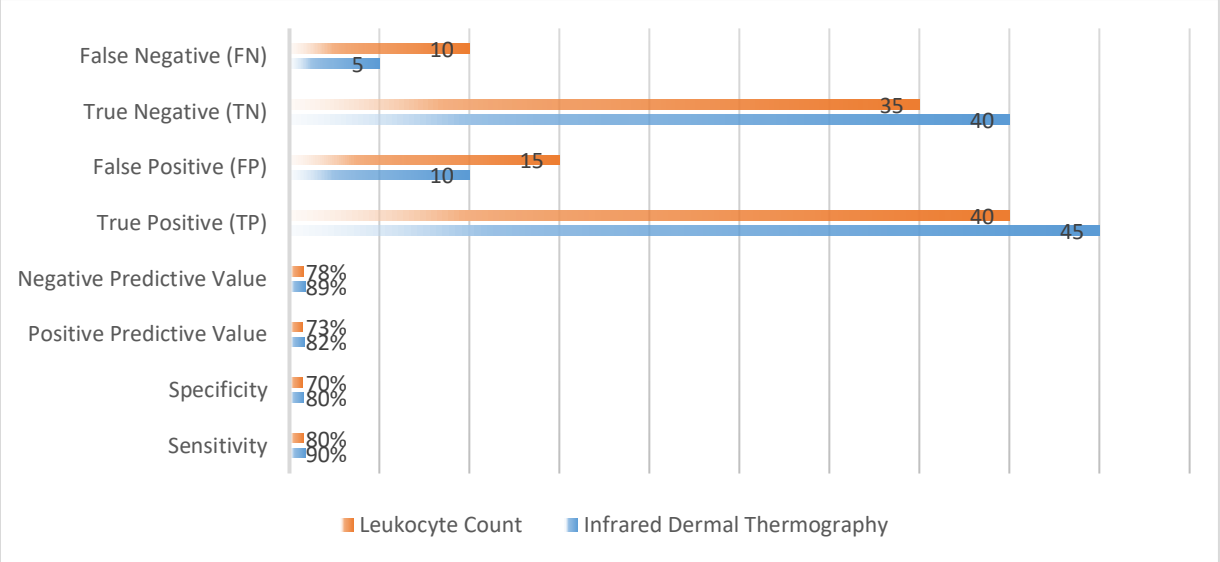

Figure 2: Diagnostic Parameters of Infrared Dermal Thermography and Leukocyte Count in Detecting Diabetic Foot Infection

Based on these findings, Infrared Dermal Thermography demonstrated superior diagnostic accuracy with higher sensitivity, specificity, PPV, and NPV compared to Leukocyte Count. These results suggest that Infrared Dermal Thermography is a more reliable method for detecting diabetic foot infections, though both methods play a valuable role in clinical diagnosis.

Discussion

Diabetic foot infection (DFI) is a major complication among individuals with diabetes, and early diagnosis is essential to prevent severe outcomes, such as amputations. Two commonly used diagnostic methods are Infrared Dermal Thermography (IDT), which detects localized temperature changes associated with infection, and leukocyte count (LC), a systemic marker for infection. Previous studies, such as those by Liu et al. (2020) and Rajab et al. (2023), have established the diagnostic relevance of both methods in detecting DFIs, with each offering unique insights into localized and systemic inflammatory responses.[18,19]

This study aimed to compare the diagnostic accuracy of IDT and LC in detecting DFIs and to determine which method is more reliable for clinical use. The central research question addressed the effectiveness of IDT in relation to LC, particularly in identifying early infection and inflammation. Our findings indicate that IDT demonstrated a sensitivity of 90% and a specificity of 80%, while LC showed a sensitivity of 80% and specificity of 70%. These results suggest that IDT may be more effective in early detection, particularly in identifying localized inflammation in diabetic foot infections.

An important discovery in this study is the nearly comparable predictive power of IDT and LC, despite their fundamentally different diagnostic approaches. With regression coefficients of 0.45 for IDT and 0.60 for LC, this study reveals that IDT can serve as a reliable non-invasive tool, potentially matching the diagnostic effectiveness of the traditionally used leukocyte count. Unexpectedly, IDT's diagnostic performance in detecting DFIs approached that of LC, which has long

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been considered the standard for infection diagnosis. Given that IDT primarily detects localized temperature changes rather than systemic infection markers, the nearly equal predictive strength was a surprising outcome of this study.

These findings support previous research that highlights IDT's potential for early diagnosis of infections. Similar studies by Ramirez-GarciaLuna et al. also found a significant correlation between elevated skin temperature and clinical signs of infection, reinforcing the role of thermography in detecting early inflammatory changes.[20]

However, our results contradict earlier findings that Favor LC as a more reliable diagnostic method for DFIs. For instance, research by Gulati et al. (2022) suggested that systemic infection markers like LC are superior to localized measurements such as IDT.[21] Our study challenges this conclusion by demonstrating that IDT can perform equally well in early infection detection.

One explanation for IDT's strong diagnostic performance may lie in its ability to detect subtle temperature changes associated with localized inflammation, which often precede systemic immune responses measurable by LC. This makes IDT particularly effective for detecting early-stage infections when systemic markers might still be within normal ranges. Despite these promising findings, caution is warranted when interpreting the results. IDT readings can be influenced by factors such as diabetic neuropathy, which may alter blood flow and temperature in the foot without an underlying infection. Clinicians should, therefore, use IDT results in conjunction with other clinical markers to avoid misdiagnosis.

Based on these findings, a general hypothesis for future investigation could be that IDT, when used in combination with systemic markers like LC, offers a more comprehensive approach to diagnosing DFIs. This multi-modal diagnostic strategy could improve early detection and patient outcomes by addressing both localized and systemic infection signs.

The implications of this study are significant for clinical practice. The use of IDT as a non-invasive, rapid diagnostic tool could enhance early diagnosis of DFIs, potentially reducing the need for invasive procedures and improving patient management. Incorporating IDT into routine screening for high-risk diabetic patients could lead to earlier interventions and better outcomes.

These findings emphasize the complementary role that IDT can play alongside traditional methods like LC. While LC provides systemic insights into infection severity, IDT offers a unique perspective by capturing localized temperature increases, which can serve as an early warning signal for developing infections.

Future research should focus on expanding the sample size and including a broader patient population to validate these results further. Additionally, studies could explore combining IDT with other diagnostic markers, such as inflammatory cytokines, to enhance diagnostic precision. Longitudinal studies examining patient outcomes after IDT-based diagnoses would also provide valuable insights into its long-term clinical effectiveness.

Implications of the findings of this study

The findings of this study carry significant implications for both clinical practice and future research in the diagnosis of diabetic foot infections (DFI). The demonstrated efficacy of Infrared Dermal Thermography (IDT) as a non-invasive, rapid diagnostic tool offers a potential shift in clinical protocols, allowing for earlier detection and management of infections. By integrating IDT into routine screenings, clinicians may be able to intervene at earlier stages, thereby reducing complications such as amputations. Additionally, the strong correlation between IDT and leukocyte count (LC) emphasizes the potential for using these tools in combination, enhancing diagnostic accuracy by capturing both localized and systemic signs of infection.

Strengths and Limitations of the Study

One of the key strengths of this study is the direct comparison between a non-invasive method (IDT) and a systemic marker (LC), providing a comprehensive evaluation of diagnostic tools for DFIs. The study's use of both sensitivity and specificity metrics offers a clear understanding of the accuracy of each method. However, there are limitations that should be considered. The sample size, while adequate for preliminary conclusions, may limit the generalizability of the findings. Additionally, factors such as neuropathy or vascular conditions that could influence IDT readings were not fully accounted for, which might affect the reliability of the results in certain patient populations.

Conclusion

This study aimed to assess and compare Infrared Dermal Thermography (IDT) and leukocyte count (LC) for diagnosing diabetic foot infections (DFIs). We found that IDT, with a sensitivity of 90% and specificity of 80%, is a promising non-invasive tool for early infection

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detection, complementing LC, which showed lower sensitivity and specificity. These results highlight IDT's potential to enhance early diagnosis and management of DFIs. While IDT demonstrates significant potential, the study's limitations include a small sample size and lack of exploration into factors like diabetic neuropathy. Future research should involve larger samples and investigate IDT's integration with other diagnostic methods. For practice, incorporating IDT alongside traditional diagnostics could improve patient care and outcomes in diabetic foot management.

Declarations

Ethical Consideration: This research has been approved by the Ethics Committee of the Ministry of Health Polytechnic Sorong, with approval number DM.03.1/4.1/178/2024. All research procedures have been conducted following the principles of the Helsinki Declaration.

Authors' Contribution:

Conceptualization: ACM. Literature search and Data collection: ACM, research assistants. Data analysis: ACM. Writing of manuscript: ACM. Review of the manuscript: ACM.

Conflict of interest: The authors declare no conflicts of interest.

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