Remote temperature monitoring (RTM) utilizes foot temperature as an indication of inflammation, providing an evidence-based approach to preventive diabetic foot care [1]. The established approach for RTM uses a contralateral temperature comparison of six plantar locations between the feet [2], limiting application to patients with two feet to monitor. Alternatively, other temperatures can serve as comparators for patients who have only one sound foot available for monitoring, such as those who have a bandaged wound on one foot or who have had a high-level amputation.

Perhaps surprisingly, given the increased clinical attention during treatment, a recently peer-reviewed abstract [3] suggests high incidence of diabetic foot ulcers (DFU) (0.41 DFU/ulcer-year) for patients already being treated for an unhealed diabetic foot ulcer. Multiple studies suggest DFU recidivism often occurs to the sound limb.

Patients who have suffered lower extremity amputation (LEA) also have elevated risk of complications to the sound foot, as demonstrated in Figure 1. Approximately 50% of those with proximal lower extremity amputation (LEA) suffer reamputation to the sound foot within 5 years. Thus, in order to prevent complications to the sound foot for those with LEA and those being treated for a DFU, RTM of a single foot provides an avenue to prevention.

Figure 1. High Risk of Complication to the Contralateral Limb after a LEA

In the absence of a contralateral control, we considered a unilateral approach with ipsilateral temperature comparison. This allows for temperatures to be compared among the six keypoints on a single foot, which sample the angiogenesis well. Ambient temperature can also be used as a control in the absence of a contralateral comparator [4], which is especially helpful if inflammation manifests as elevated temperature across all angiogenesis. Due to the impaired thermoregulation in diabetic feet, abnormal temperatures in one of the plantar angiogenesis in relation to other angiogenesis on the same foot can indicate the impending threat of ulceration.

Introduction

We aim to utilize both of these alternative RTM comparison approaches to identify inflammation preceding DFU detection for high-risk patients experiencing on-going wound treatment and patients who have previously suffered major lower extremity amputation [5, 6].

Figure 2. Conventional Thermometry

Definition 1: Monitoring Approach

A patient is deemed to have inflammation if there is:

- an ipsilateral temperature range (ITR), or difference between maximum and minimum temperatures over six plantar keypoints, exceeding the ITR threshold.

- or -

an ambient temperature difference (ATD), or difference between the median temperature over the six plantar keypoints and the ambient temperature, exceeding the ATD threshold.

Methods

We can secondary analysis from a multicenter study (NCT02647746) with 129 participants, each of whom had a history of diabetic foot ulcers [7]. Over 34 weeks, participants received standard care in addition to daily remote temperature monitoring with an in-home telemeteric mat (Podometrics RTM System; Somerville, MA). Considering the primary outcome of interest was DFU recurrence, patients and investigators were blind to the thermometric data.

For this single foot RTM investigation, we treated the thermometric data and outcomes for each foot independently. We examined the range in temperature across the four plantar foot angiogenesis, which we refer to as the ipsilateral temperature range (ITR). We also considered differences among the angiosomal temperatures and ambient temperature, referred to as the ambient temperature difference (ATD). Definition 1 demonstrates a monitoring approach.

Definition 1: Monitoring Approach

A patient is deemed to have inflammation if there is:

- an ipsilateral temperature range (ITR), or difference between maximum and minimum temperatures over six plantar keypoints, exceeding the ITR threshold.

- or -

an ambient temperature difference (ATD), or difference between the median temperature over the six plantar keypoints and the ambient temperature, exceeding the ATD threshold.

Results

During the duration of the study, 37 participants experienced ulceration for a total of 53 DFU occurrences. Of those 37 participants, 8 suffered DFU to both feet during the trial, leaving 29 participants of interest with one foot with DFU. Four ITR thresholds were considered for sensitivity and specificity that may serve as reference in clinical practice for approaches to patient monitoring. For example, at ITR threshold ITR, the RTM system accurately identified 91% of non-acute plantar DFU with a 44 day lead time and 55% false positive rate. These data extrapolate to 3.9 notifications per year for each participant, assuming constant true-positive and false-positive rates observed in trial continue over one year. The data in Table 1 can be interpolated to estimate efficacy levels at different thresholds.

Table 1. Accuracy of DFU Prediction using the Unilateral Approach

<table>
<thead>
<tr>
<th>ITR Threshold</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>Lead Time (days)</th>
<th>Positive Predictive Value</th>
<th>Negative Predictive Value</th>
<th>Alerts (per participant-year)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ITR1</td>
<td>97%</td>
<td>91%</td>
<td>44</td>
<td>12%</td>
<td>98%</td>
<td>4.8</td>
</tr>
<tr>
<td>ITR2</td>
<td>80%</td>
<td>66%</td>
<td>38</td>
<td>16%</td>
<td>96%</td>
<td>3.2</td>
</tr>
<tr>
<td>ITR3</td>
<td>53%</td>
<td>45%</td>
<td>31</td>
<td>22%</td>
<td>94%</td>
<td>2.9</td>
</tr>
<tr>
<td>ITR4</td>
<td>37%</td>
<td>31%</td>
<td>30</td>
<td>26%</td>
<td>94%</td>
<td>2.7</td>
</tr>
</tbody>
</table>

Conclusions

We presented the accuracy of an essential remote temperature monitoring approach for those with only one foot available for monitoring, which constitutes a high-risk cohort. In circumstances where the conventional contralateral approach with two feet cannot be applied, ipsilateral foot temperature comparisons or comparisons between foot temperature and ambient temperature allow for normal differences in temperature to be identified. This remote temperature monitoring approach was found to correctly identify 91% of plantar DFU with a 44 day lead time in our data. Ultimately, daily remote temperature monitoring for this extremely high-risk patient population may greatly reduce ulceration of the sound foot, subsequent resource allocation, and risk of mortality.

Acknowledgements

Katherine A. Wood contributed to the poster copy and layout.

References

[1] Lawrence A. Lavery, DPM, MPH • Brian J. Petersen, MBA, MS • Jonathan D. Bloom, MD • Gary M. Rothenberg, DPM

We can secondary analysis from a multicenter study (NCT02647746) with 129 participants, each of whom had a history of diabetic foot ulcers [7]. Over 34 weeks, participants received standard care in addition to daily remote temperature monitoring with an in-home telemeteric mat (Podometrics RTM System; Somerville, MA). Considering the primary outcome of interest was DFU recurrence, patients and investigators were blind to the thermometric data.

For this single foot RTM investigation, we treated the thermometric data and outcomes for each foot independently. We examined the range in temperature across the four plantar foot angiogenesis, which we refer to as the ipsilateral temperature range (ITR). We also considered differences among the angiosomal temperatures and ambient temperature, referred to as the ambient temperature difference (ATD). Definition 1 demonstrates a monitoring approach.

Definition 1: Monitoring Approach

A patient is deemed to have inflammation if there is:

- an ipsilateral temperature range (ITR), or difference between maximum and minimum temperatures over six plantar keypoints, exceeding the ITR threshold.

- or -

an ambient temperature difference (ATD), or difference between the median temperature over the six plantar keypoints and the ambient temperature, exceeding the ATD threshold.