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Predictive value of forefoot plantar pressure to predict reulceration in patients at high risk

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ABSTRACT

Aims: To analyze a plantar pressure cut-off point for diabetic foot reulceration beneath the metatarsal heads in patients with previous forefoot amputation.
Methods: A one-year prospective study was conducted in a total of 105 patients at high risk for foot ulceration. Peak plantar pressure (PPP) and pressure-time integral (PTI) in the entire foot, the forefoot region, and each metatarsal head separately were registered. ROC curves were used to select the optimal diagnostic pressure cut-off points. Patients were follow-up monthly or until the development of an ulcer event.
Results: A total of 52 (49.5%) patients developed a reulceration. Using ROC analyses for PPP in the full-foot and in the forefoot, did not predict reulceration beneath the metatarsal heads. Analyzing separately each metatarsal head all patients with values greater than or equal to 20.8 N/cm^2 at the 1st, 18.62 N/cm^2 for the 2nd, 18.85 at the 3rd, 17.88 at the 4th, and 12.2 at the 5th metatarsal heads will suffer a reulceration despite the use of orthopedic treatment with optimum values of sensitivity (from 100 to 87.5) and specificity (from 83.2 to 62.8).
Conclusion: Barefoot pressures beneath the metatarsal heads should be analyzed separately to predict the region at risk of reulceration.

1. Introduction

Reulceration has become one of the biggest unresolved issues in patients with diabetes mellitus (DM), especially those with a history of amputation. After the resolution of a foot ulcer, recurrence is a common issue that affects almost 60% of patients within one year of the first ulcer healing [1–3]. This makes it necessary to approach a current problem with patients in remission that supposes a greater number of patients than those with an active ulcer [3].

Elevated plantar pressure has been established as an essential risk factor for ulceration in patients with DM. The prevention guidelines from the International Working Group on Diabetic Foot (IWGDF) focus on evaluating plantar pressure assessment to reduce this modifiable risk factor [4]. Foot peak plantar pressure (PPP) is significantly higher in patients who developed ulcers than those without DFU [5,6], with data ranging from 95.5 to 83.1 N/cm^2 in ulcerated patients and 85.1 to 62.7 N/cm^2 in non-ulcerated patients depending on the population and measurement devices employed. However, whether there is a significant difference in PPP between patients with a history of ulceration or amputation (IWGDF risk 3) and patients who had neuropathy and deformity without a history of ulceration or amputation (IWGDF risk 2) is unknown [5].

Additionally, previous studies evaluating diabetic foot pressures to identify a threshold pressure predictive of ulceration [5–8] have established foot pressures greater than 110 N/cm^2 for every subject with DM and a history of foot ulceration [7]. Nevertheless, the threshold pressure to identify a DFU remains unclear. The optimal cut-off points for PPP to identify DFU range above 65 N/cm^2 [8] to over 87.5 N/cm^2 [5] in the foot and around 70 N/cm^2 [6] for the forefoot area.

Despite these data, the sensitivity and specificity of plantar pressure in identifying DFUs are relatively low, leading investigators to label peak pressure as a poor predictor [9]. To date, none of these studies have evaluated plantar pressure thresholds in patients with a history of metatarsal head resection, which has become one of the main risk

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factors for developing a reulceration. Identifying an optimal PPP cut-off point for patients at high risk of foot ulcer occurrence would be an interesting preventive tool that would allow clinicians to predict reulceration in patients with a previous forefoot amputation.

Therefore, the principal aim of this study was to identify a cut-off point with an optimal combination of sensitivity and specificity for diabetic foot reulceration beneath the metatarsal heads in patients with previous metatarsal head resection.

2. Research design and methods

2.1. Subjects

This prospective study was conducted between May 2018 and February 2022 on a total of 105 patients who were at high risk for foot ulceration in a specialized diabetic foot unit. Inclusion criteria were confirmed type 1 or 2 DM [10], age > 18 years old, classified as high-risk patients (risk 3) according to the IWGDF risk classification due to at least one metatarsal head resection [4]. Exclusion criteria were patients with an active ulcer during the examination, transmetatarsal or major amputation, critical limb ischemia [11], amputation of the contralateral limb, and the need for walking aids.

This study was approved by the ethics committee of our teaching hospital in May 2018 (Code: 18/227-E). Before their inclusion in this study, all patients provided their written informed consent in accordance with the principles of the Declaration of Helsinki [12].

2.2. Clinical evaluation

The patient́s medical history was assessed at baseline, including diabetes type, mean duration of diabetes, associated comorbidities, HbA1c (%) values in the last blood test, and history of minor forefoot amputation. Peripheral arterial disease (PAD) was defined as the absence of both pulses and/or an ankle-brachial index (ABI) > 0.9 or ABI ≤ 0.9 and ankle systolic blood pressure (ASBP) ≥ 70 mmHg, or toe systolic blood pressure (TSBP) of 50 mmHg. In patients with medial arterial calcification (ABI > 1.4), we considered PAD a toe-brachial index (TBI) < 0.7 [13].

Patients were consecutively included when healing after the conservative surgery procedure.

This procedure consists of a metatarsal head resection performed by bone resection in the surgical neck of the metatarsal, and the metatarsal head was removed completely with the dorsal or plantar approach [14].

Additionally, biomechanical and forefoot deformities were identified with the patient in a standing position. We considered the presence of hallux abductus valgus (HAV), claw toe, Taylor's bunion, and plantar bony prominence of the metatarsal head [15].

2.3. Plantar pressure measurement

A dynamic pressure measurement system, FootScan® software (RScan International, Belgium), was used to record PPP (N/cm^2) and PTI ($N/cm^2/s$). This process used 2-m-long platforms with 4 sensors/cm^2 and a 3D-Box interface synchronized with the motion capture system. Patients were instructed to walk barefoot for over three minutes before recovering the plantar pressure to accommodate the patient to normal gait and speed. After this, four registers were taken to calculate the mean of both measurements (PPP and PTI) with a two-step approach to the platform [16]. The PPP and PTI were recorded at five locations in the forefoot: first, second, third, fourth, and fifth metatarsal heads. The region corresponding to the metatarsal head resected was not analyzed. The highest value of the four remaining metatarsals was selected [17].

2.4. Follow-up

Patients were follow-up for one year after the inclusion or until the development of an ulcer event. Patients were assessed monthly to debride high-risk points and review the risk factors following the IWGDF recommendations [4].

All patients wore a custom-made insole consisting of a 5-mm microcork base added to a 6-mm mid-layer of ethylene-vinyl acetate (EVA, shore 40A). In the areas identified at risk because of the highest PPP and PTI, 5 mm EVA was removed and padded with 3 mm of Plastazote®, shore 25A [18]. In addition, the subject was fitted with an extra-deep shoe consisting of a rigid rocker outsole with a pivot point at 60% of their shoe length, a rocker angle of 20°, and a stretchy upper material [19].

Reulceration in the forefoot area was defined as developing a new ulcer located in a different anatomical site [20].

2.5. ROC curves

The primary outcome measure was reulceration to define a cut-off

Table 1
Patients' baseline characteristics.

Baseline characteristics	All patients (N = 105)	Ulceration Patients (n = 52)	Non-Ulceration Patients (n = 53)	P-value
Male, n (%)	96 (91.4%)	44 (84,6%)	52 (98.1%)	**0.014***
Female, n (%)	9 (8.6%)	8 (15,4%)	1 (1.9%)	
Type 1 Diabetes, n (%)	21 (20%)	43 (82.7%)	12 (22.6%)	0.495
Type 2 Diabetes, n (%)	84 (80%)	9 (17.3%)	41(77.4%)	
Retinopathy, n (%)	45 (42,5%)	22 (42.3%)	23 (43.4%)	0.910
Hypertension, n (%)	92 (87.6%)	48 (92.3%)	44 (83%)	0.148
Nephropathy, n (%)	25 (23.8)	12 (23.1%)	13 (24,5%)	0.861
Cardiopathy, n (%)	41 (39%)	23 (44.2%)	18 (34%)	0.281
PAD, n (%)	42 (40%)	20 (38.5%)	22(41.5%)	0.750
Presence of pedis pulse, n (%)	62 (59%)	31 (59.6%)	31 (58.5%)	0.980
Presence of tibialis posterior pulse, n (%)	58 (55.2%)	30 (57.7%)	28 (52.8%)	0.685
Ankle brachial pressure index, mean ± SD	1.08 ± 0.3	1.13 ± 0.32	1.02 ± 0.30	0.313
Toe brachial pressure index, mean ± SD	0.7 ± 0,.3	0.7 ± 0.22	0.72 ± 0.25	0.66
Mean age ± SD (years)	66.13 ± 9.72	66.54 ± 8.94	65.74 ± 10.49	0.674
Body mass index (kg/m^2), mean ± SD	28.85 ± 5.14	28.24 ± 3.70	29.45 ± 6.21	0.229
Diabetes mellitus (years), mean ± SD	20.80 ± 11.18	19.11 ± 11.30	22.45 ± 10.92	0.127
Glycated hemoglobin (%), mean ± SD	7.70 ± 1.41	7.47 ± 1.06	8.06 ± 1.61	0.08
Foot characteristics				
Hallux abductus valgus, n (%)	11 (10.5%)	8 (15.4%)	3 (5.7%)	0.105
Tayloŕs bunion, n (%)	19 (18.1%)	8 (15.4%)	11 (20.8%)	0.475
Hammer toe, n (%)	71 (67.6%)	40 (76.9%)	31 (58.5%)	**0.04***
Plantar prominence, n (%)	83 (79%)	49 (94.2%)	34 (64.2%)	**<0.001***

PAD, peripheral arterial disease; SD, standard deviation; kg, kilograms; m^2, squared meters; PPP, peak plantar pressure; PTI, pressure-time integral. *P < 0.05 indicates statistical significance.

Table 2
Baseline peak plantar pressure and pressure-time integral.

Baseline pressure distribution	All patients (N = 105)	Ulceration Patients (n = 52)	Non-Ulceration Patients (n = 53)	P-value
PPP foot	99.63 ± 35.08	104.94 ± 38.63	94.43 ± 30.70	0.125
PPP forefoot area (1st – 5th MH)	68.05 ± 32.84	74.59 ± 35.92	61.63 ± 28.41	**0.043***
PTI foot	34.86 ± 15.16	36.97 ± 16.03	32.80 ± 14.11	0.161
PTI forefoot area (1st – 5th MH)	22.82 ± 13.10	25.57 ± 14.40	20.13 ± 11.19	**0.033***

PPP, peak plantar pressure; PTI, pressure-time integral. *P < 0.05 indicates statistical significance.

point of pressure measurement that optimally combines sensitivity and specificity to identify the diagnostic accuracy of plantar pressure analyses on the detection of an ulcer event in the plantar aspect of the metatarsal heads in patients at high risk for foot ulceration.

2.6. Statistical analyses

The normality of all continuous variables was verified using the Kolmogorov-Smirnov test. Normally distributed variables (Kolmogorov-Smirnov test with p ≥ 0.05) were reported as means and standard deviations. To explore differences in clinical features between patients with and without reulceration, the chi-square and Student's t-tests were used for the categorical for quantitative variables, respectively. ROC curves were used to select the optimal diagnostic cut-off points on the pressure measurement (PPP and PTI) scales, which is a graphical method of representing sensitivity and specificity for a given test. In addition, positive predictive value (PPV), negative predictive value (NPV), positive likelihood ratio (PLR), and negative likelihood ratio (NLR) were calculated for PPP and PTI.

All statistical analyses were performed using SPSS statistics version 25.0 for Mac OS (SPSS, Chicago, IL, USA). P-values < 0.05 were considered statistically significant with a confidence interval (CI) of 95%.

3. Results

A total of 105 patients were included in the present study. Baseline data on demographic, foot characteristics, and pressure distribution are shown in Table 1.

We did not find differences between PPP and PTI at baseline in the entire foot of patients who suffered a reulceration. Despite this, as expected, patients who suffered from a reulceration event had higher PPP and PTI in the forefoot area than those without an ulceration event (Table 2.)

3.1. Main outcome

Of the entire population, 52 (49.5%) patients developed a reulceration within one year of the follow-up period. The ROC analyses for PPP in the entire foot and the forefoot indicated that the area did not predict reulceration beneath the metatarsal heads (Fig. 1).

By separately analyzing each metatarsal head, we found an optimal prediction model based on cut-off points for PPP and PTI beneath each

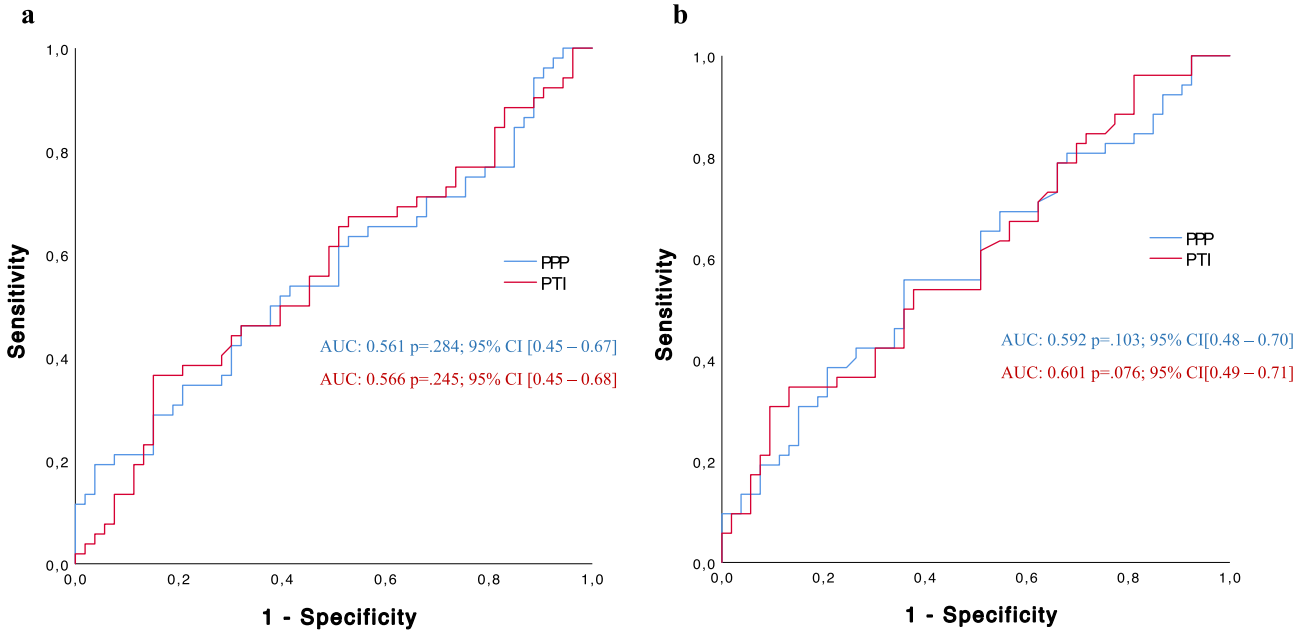

Fig. 1. ROC curves for PPP and PTI; **(a)** in the foot and **(b)** forefoot area. AUC, area under the curve; PPP, peak plantar pressure; PTI, pressure-time integral.

Table 3
Baseline peak plantar pressure and pressure–time integral.

Metatarsal head	Cut-off point (N/cm^2)	Sensitivity (%)	Specificity (%)	PPV	NPV	PLR	NLR
1st	20.58	95.2	71.4	0.76	0.93	3.27	0.07
2nd	18.62	90	62.8	0.70	0.86	2.36	0.16
3rd	18.85	90	63.2	0.70	0.86	2.43	0.15
4th	17.88	87.5	82.5	0.83	0.87	4.83	0.16
5th	12.2	100	83.2	0.85	1	5.88	0

PPV, positive predictive value; NPV, negative predictive value; PLR, positive likelihood ratio; NLR, negative likelihood ratio.

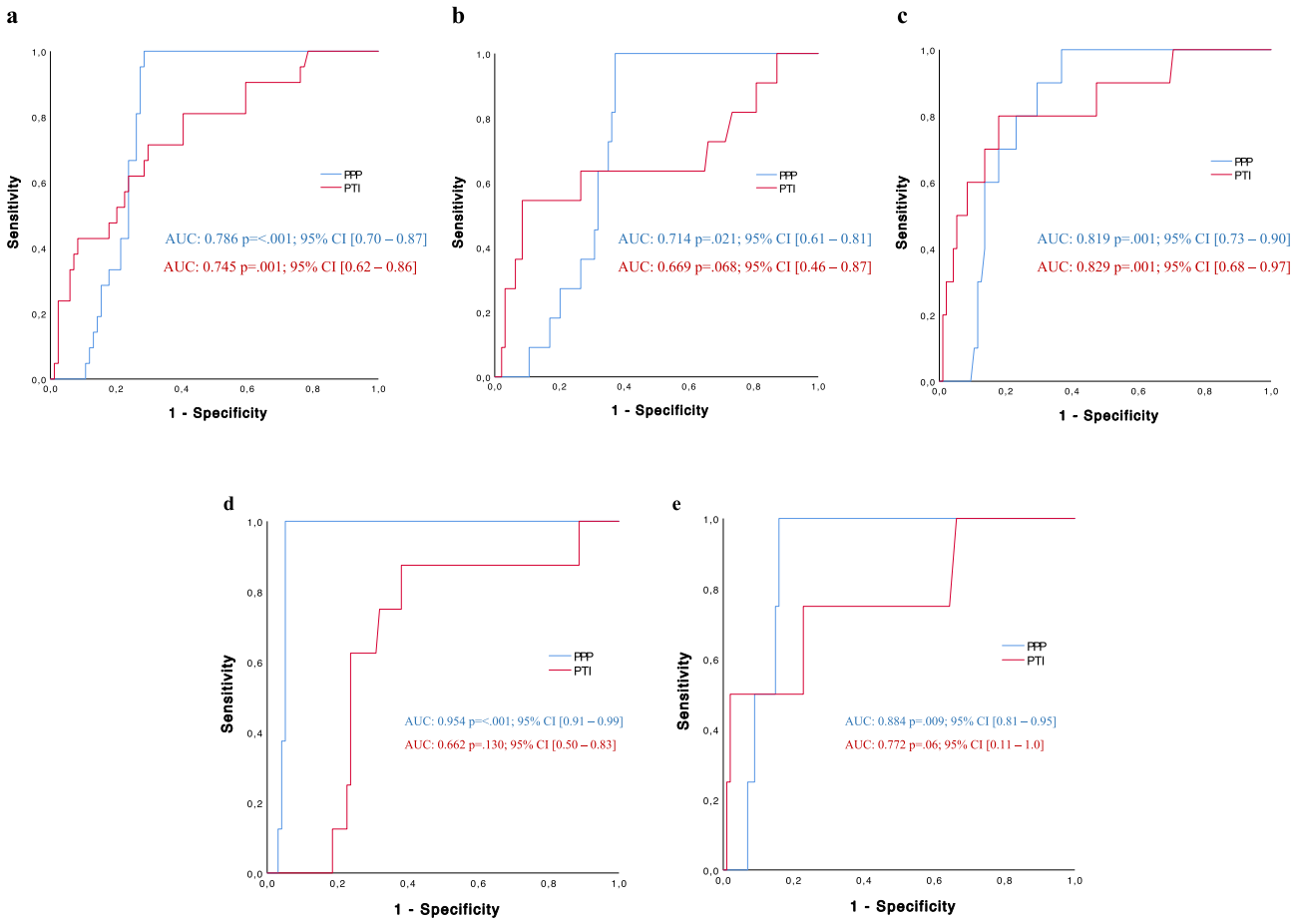

Fig. 2. ROC curves for 1st to 5th metatarsal heads. AUC, area under the curve; PPP, peak plantar pressure; PTI, pressure-time integral. **(a)** 1st metatarsal head; **(b)** 2nd metatarsal head**; (c)** 3rd metatarsal head; **(d)** 4th metatarsal head; **(e)** 5th metatarsal head.

metatarsal head to detect a DFU using a risk point that balanced sensitivity and specificity (Table 3, Fig. 2).

4. Discussion

The present study identified an optimal prediction model based on cut-off points for PPP beneath each metatarsal head independently to detect the risk point determined by a balance of sensitivity and specificity in DFUs in patients with a metatarsal head resection. However, plantar pressures in the entire foot and forefoot area were not suitable for detecting risk in patients who develop a reulceration in the medium- to long-term due to relatively low sensitivity and specificity of PPP.

As expected, in the present study, patients who developed a reulceration event had increased forefoot PPP (74.59 N/cm^2 vs. 61.63 N/cm^2, p = 0.043) and PTI (25.57 N/cm^2 vs. 20.13 N/cm^2, p = 0.033) values compared with non-ulceration patients at baseline. Similarly, Armstrong et al. [6] showed significantly higher PPP scores in the forefoot of diabetic patients with a history of DFU 83.1 N/cm^2 compared with patients with DM without a history of DFU 62.7 ± 21.4 N/cm^2. However, they do not include amputation patients. It empowers the current research because high-risk patients (IWGDF-risk 3) with previous minor amputation have shown to develop major complications compared with non-amputation patients.

Lavery et al. [5] demonstrated higher PPP in the foot in patients who developed a DFU of 95.5 N/cm^2 compared with patients who did not develop ulcers (85.5 N/cm^2; p < 0.001) in a 24-month follow-up period. Our PPP values were higher, with an average PPP of 104.94 N/cm^2 in reulceration patients and 94.43 N/cm^2 in non-reulceration patients without a statistical association. This could be explained by the sample size of the high-risk patients included in our research compared with others.

Additionally, these previous studies have established cut-off points of plantar pressure of 87.5 N/cm^2 in the entire foot, determined by a sensitivity of 63.5% and a specificity of 46.3% in patients at risk levels 1–3. Only one study [6] has presented a plantar pressure prediction model for neuropathic ulceration in the forefoot. They showed an optimal cut-off point of 70 N/cm^2 for detecting DFUs in the forefoot, determined by a sensitivity of 70.0% and a specificity of 65.1% in patients with a history of DFU (risk 3). In our study, pressure patterns in the entire foot or forefoot area were not well-suited for screening patients for reulceration due to the lack of statistical association.

The data from the present study support screening patients with forefoot amputation by studying the specific at-risk regions separately, as for diabetic midfoot reulceration in Charcot foot patients [21].

Cut-off point values increased progressively from the 1st to 5th metatarsal heads due to the anatomical and biomechanical function and the probability of suffering a reulceration previously described for each metatarsal head [20]. All patients with values greater than or equal to 20.8 N/cm^2 at the 1st, 18.62 N/cm^2 for the 2nd, 18.85 at the 3rd, 17.88 at the 4th, and 12.2 at the 5th metatarsal heads will suffer a reulceration despite the use of orthopedic treatment with optimum values of sensitivity (from 100 to 87.5) and specificity (from 83.2 to 62.8).

Although, the present study highlights the importance of patients' risk levels with and without diabetic foot amputation. Therefore, clinicians should precisely examine the pressure measurement location to determine the risk of reulceration.

Our results should be interpreted with caution due to some limitations. We did not evaluate anormal shear pressures that could increase

the risk for the development of factors such as a callus formation [22] and, consequently, DFU occurrence [9].

Additionally, in-shoe pressures were not analyzed; thus, footwear's influence on ulcer occurrence requires further exploration. The present study's main strength is being the first to investigate cut-off values to screen for diabetic foot reulceration in a population at high risk with a history of forefoot amputation in all cases, which represents the most complex profile of patients at high risk (IWGDF risk 3).

5. Conclusions

Barefoot pressures beneath the metatarsal heads have a better diagnostic capacity to predict the specific region at risk of reulceration. General foot and forefoot PPP were not predictive of reulceration. Clinicians should carefully evaluate the PPP beneath each metatarsal head according to the optimal prediction model identified in the study.

CRediT authorship contribution statement

Marta García-Madrid: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration,Resources, Software, validation, visualization, writing—original draft preparation, writing—review and editing. **Yolanda García-Álvarez:** Conceptualization, Formal analysis, Methodology, Project administration, Resources, supervision, writing—review and editing. **Irene Sanz-Corbalán:** Data curation, Investigation, Software, supervision. **Francisco J. Álvaro-Afonso:** Investigation, Methodology, Software. **Mateo López-Moral:** Data curation, Investigation, Software, supervision, validation, visualization, writing—review and editing. **José Luis Lázaro-Martínez:** Conceptualization, Formal analysis, Methodology, Project administration, Resources, validation, visualization, writing—review and editing.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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