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Short- and long-term risk stratification in acutely ill medical patients by implementing ankle-brachial index and pulse wave velocity in the emergency setting

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Abstract

Objective: Ankle-brachial index (ABI) and carotid-femoral pulse-wave velocity (cfPWV) are well-established surrogate markers of overall cardiovascular risk. However, their prognostic value towards short- and long-term mortality in an emergency medicine setting is yet unknown.

Approach and Results: Acutely ill medical patients systematically underwent cfPWV and ABI measurements at the emergency department of a tertiary care hospital. Patients' survival was analysed in relation to their ABI and cfPWV values at initial presentation. In total, 1080 individuals (43.7% females; 59.6 ± 17.4 years old) were enrolled. Over a median follow-up period of 24.4 months, 112 (10%) deaths were observed. 30-day mortality was 4.9% in patients with a pathological ABI and 1.4% with a normal ABI (p = .003). There was also a significant difference over the entire observational period regarding cumulative mortality (p < .001). Thirty-day mortality was 2.4% in patients with a cfPWV ≥10 m/s and .7% with a cfPWV $<10 \,\mathrm{m/s}$ (p=.025), and cumulative mortality over the whole period differed between a cfPWV \geq 10 m/s and <10 m/s as well (p < .001).

Conclusion: In acutely ill medical patients, the noninvasive ABI and cfPWV assessment at triage level facilitates initial risk stratification in the emergency setting for short- and long-term mortality. Patients with pathological ABI and cfPWV values could thus be seen as a proxy of a sicker cohort with an overall worse polyvascular situation.

Sebastian Schnaubelt and Julia Oppenauer contributed equally to this manuscript.

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KEYWORDS

ankle-brachial index, arterial stiffness, emergency department, mortality, peripheral arterial disease, pulse wave velocity

1 | BACKGROUND

Cardiovascular disease is the leading cause for acutely ill patients presenting to emergency departments (ED) worldwide. The individual patients cardiovascular risk potentially contributes to the prognosis in the emergency setting. Especially with ED overcrowding and limited resources, physicians need to rapidly identify patients at increased cardiovascular risk requiring specialized cardiovascular care.

For cardiovascular risk stratification, the anklebrachial index (ABI) and the carotid-femoral pulse wave velocity (cfPWV) are well established surrogate markers.^{2,3} The ABI is the ratio between noninvasive blood pressure recordings from the patients' ankles and upper arms, 4 and provides information on the patients' peripheral arterial perfusion.^{5,6} Simultaneously to an ABI measurement, the cfPWV can be assessed. It mirrors central arterial conditions, mainly aortic stiffness, and is increased in patients with underlying arteriosclerosis. Guidelines on the management of hypertension by the European Society of Cardiology suggest the implementation of cfPWV for the estimation of cardiovascular risk.³ Both ABI and cfPWV are noninvasive and inexpensive measures which can quickly be determined by trained nurses or technicians. Also, we have previously demonstrated the feasibility of applicability of ABI and cfPWV measurements in selected groups of patients in the busy setting of a medical emergency department, and suggested them to be integrated into the triage process.^{8,9} Even though ABI and PWV are well-known mortality predictors in general, 10,11 it is yet unknown whether and to which extent they may allow for short- and long-term risk stratification of acutely ill patients. The aim of this prospective observational study was thus to assess this gap of knowledge and provide a broad base for further investigation.

2 | METHODS

2.1 | Study design, patients and data acquisition

This prospective observational study included consecutive patients presenting to the Department of Emergency Medicine of the Medical University of Vienna, Austria (a tertiary care university hospital¹²) between November

Key points

- It is known that a reduced ankle-brachial index (ABI) and an elevated carotid-femoral pulse wave velocity (cfPWV) are surrogate markers of cardiovascular risk, but the respective prognostic value in emergency medicine has still been unclear.
- In this prospective observational cohort study on over 1000 acutely ill medical patients of an emergency department, an ABI <1.00 was observed in 31%, and a cfPWV ≥10.0 m/s was found in more than 45%, and both were independently related to short- and long-term survival.
- ABI and cfPWV could supplement patient evaluation at triage level in emergency departments, hinting at an increased polyvascular risk and short-term mortality and allowing for respective focus and resource allocation.

2018 and May 2023. The reasons for presenting to the ED were classified into, according to frequency, chest pain, dyspnea, suspected pulmonary embolism, palpitations (atrial fibrillation and atrial flutter), suspected acute renal failure and other reasons (mainly infections). The trauma department is not part of this ED, and thus no trauma patients were screened or included. In addition, patients were not screened for inclusion in case of hemodynamic or respiratory instability because ABI and cfPWV measurements would have potentially resulted in a delay of necessary life-saving measures. Moreover, pregnant patients and those below the age of 18 years were not included. Both patients who were discharged home after having been seen in the ED and those who were admitted to a hospital ward afterwards were included. Demographic characteristics, medical histories and clinical and laboratory data were systematically assessed and collected partially prospectively at inclusion and partially retrospectively in a respective case report form. For survival analysis and causes of death, respective data were derived from institutional records, as well as from the national mortality registry, the Austrian Statistics on Deaths (Statistik Austria). This study was performed in accordance with

good clinical practice guidelines and the declaration of Helsinki. The study was approved by the institutional Ethics Committee of the Medical University of Vienna, Austria (no. 2197/2017, approval 01/2018). Data reporting was performed according to STROBE guidelines.

2.2 | Ankle-brachial index and pulse wave velocity

ABI and cfPWV were measured once following the initial triage assessment during the stay in the ED. The time delay from triage assessment to ABI and PWV measurement was mostly within 90 min. ABI measurements were, according to previous literature and reports, categorized into normal ABI (≥1.0), borderline ABI (.91–.99) or low ABI (\leq .90). For determination of 'normal' versus 'pathological' ABI and respective mortality analyses, the cut-off was chosen as .91.2,13,14 Also, cf-PWV measurements were grouped accordingly $(<10 \text{ m/s vs.} \ge 10 \text{ m/s})$. ABI and cfPWV were determined by using a certified oscillometric ABI- and PWVdevice (BOSO ABI Systems 100 PWV®, Bosch&Sohn GmbH, Jungingen, Germany). All measurements were performed in a supine patient position after a resting period of 10 min. Sphygmomanometer cuffs were placed around both patients' upper arms and lower limbs just above the ankles. Trained study personnel performed the measurements, supervised by two experienced investigators. For ABI calculation, the device divided the oscillometrically determined systolic ankle blood pressure by the oscillometrically determined systolic brachial blood pressure. In case of differences between the systolic brachial blood pressure values of both sides, the higher value of the systolic brachial blood pressure was used for the calculation of the ABI for each limb. For the assessment of the cfPWV, the device determined the time shift between the capturing of peripherally recorded pulse waves. To calculate the cfPWV, the patients' height was taken into account. CfPWV values were calculated separately for each leg, with the higher values being used for data analyses. To determine variability, three repetitive measurements in 10 volunteers had been conducted previously, demonstrating a mean coefficient of variation of 2.8% for cfPWV.

2.3 | Outcomes

The primary outcome was the impact of low/pathological ABI (≤.90) on patients' short-term (30 days) mortality which is relevant in the emergency setting. Secondary outcomes were the impact of a pathological cfPWV on

patients' mortality, as well as the co-prevalence of risk factors in the study population.

2.4 | Statistical analysis

Categorial data are presented as absolute and relative frequencies and were compared among subgroups using chi-square test. Continuous variables are described using means \pm standard deviations (SD) or medians and the respective interquartile ranges (IQR) and were compared via the Mann-Whitney U test. Cumulative hazard functions were estimated and plotted (Kaplan-Meier plots), including their 95% confidence intervals (CI), for the different groups. The log-rank test was used to check for significant differences. Associations of mortality with potential explanatory factors (cardiovascular risk factors: age, sex, arterial hypertension, dyslipidemia, diabetes, chronic kidney disease, cerebrovascular disease, previous stroke, coronary artery disease and previous acute coronary syndrome) were analysed using simple logistic regression models. Explanatory factors with odds ratios significantly different from 1 (at $p \le .05$) were included in a multiple logistic regression model (ABI and cfPWC). In addition, a multivariate model containing all cardiovascular risk factors was calculated. We assumed statistical significance through two-sided pvalues of <.05 and performed calculations with the statistical software R (RStudio Version 1.2.5033, RStudio Inc., Boston, MA, U.S.A.).

3 | RESULTS

3.1 Study population characteristics

Between November 2018 and May 2023, 1180 acutely ill medical patients were enrolled during their presentation to the respective ED. After excluding 100 patients due to missing values (lab values, follow up, etc.), a total of 1080 patients were included in the main analysis. In this study population (n=1080), the mean age was 59.6 years (SD 17.4), and patients were predominantly male (56.3%).

The main reason for the ED visits was chest pain with 62.2% (n = 672/1080). 6.9% (n = 74/1080) presented with dyspnea and 4.5% (n = 49/1080) with suspected acute pulmonary embolism. Sixty-nine patients complained of palpitations (6.4%) with atrial fibrillation/atrial flutter as the underlying cause. Acute renal failure was suspected in 201 patients (18.6%). Ninety-seven of the 1080 patients (9.0%) presented to the ED for another reason, and this group mostly included suspected infections such as COVID-19 or influenza. Hemodynamic

	Study population	ABI≥1	ABI .9199	ABI≤.9		
	n = 1080	n = 748	n = 189	n=143		
Category	n = 1080 (100%)	n = 748 (69%)	n = 189 (18%)	n = 143 (13%)	<i>p</i> -Value	
Age [years]	59.6 ± 17.4	56.5 ± 16.3	62.6 ± 19.1	70.6 ± 15.2	<.001	
Female sex	472 (43.7)	304 (40.6)	96 (50.8)	72 (50.3)	<.001	
BMI [kg/m ²]	27.4 ± 5.5	27.4 ± 5.5	27.5 ± 5.7	27.5 ± 5.4	.974	
Comorbidities						
Arterial hypertension	553 (51.2)	330 (44.1)	120 (63.5)	103 (72.0)	<.001	
Dyslipidemia	325 (30.1)	187 (25.0)	71 (37.6)	67 (46.9)	<.001	
Diabetes mellitus type 2	202 (18.7)	97 (13.0)	53 (28.0)	52 (36.4)	<.001	
Chronic kidney disease	95 (8.8)	38 (5.1)	23 (12.2)	34 (23.8)	<.001	
Peripheral arterial disease ^a	57 (5.3)	11 (1.5)	10 (5.3)	36 (25.2)	<.001	
Cerebrovascular disease	55 (5.1)	24 (3.2)	9 (4.8)	22 (15.4)	<.001	
Previous stroke	54 (5.0)	24 (3.2)	13 (6.9)	17 (11.9)	<.001	
Atrial fibrillation	136 (12.6)	77 (10.3)	34 (18.0)	25 (17.5)	.002	
Coronary artery disease	209 (19.4)	115 (15.4)	40 (21.2)	54 (37.8)	<.001	
Previous ACS	169 (15.6)	92 (12.3)	34 (18.0)	43 (30.1)	<.001	
Ever smoker	372 (34.4)	253 (33.8)	67 (35.4)	52 (36.4)	.961	
Laboratory data						
Triglycerides [mg/dL]	140 ± 110	137 ± 105	141 ± 87	156 ± 148	.084	
LDL-cholesterol [mg/dL]	99 ± 45	105 ± 43	88 ± 51	74 ± 41	.039	
Lipoprotein(a) [mg/dL]	55 ± 71	51 ± 69	46 ± 53	93±85	.077	
Vascular hemodynamics						
cfPWV [m/s]	10.1 ± 2.9	9.7 ± 2.6	11.0 ± 3.3	12 ± 3.4	<.001	
ABI	$1.04\pm.1$	$1.1\pm.1$	$.9 \pm .0$	$.8\pm.1$	-	

TABLE 1 Demographic and clinical characteristics of 1080 acutely ill medical patients with ankle-brachial index measurements.

Note: Categorial data are presented as counts and percentages, continuous data as means and standard deviations.

Abbreviations: ABI, ankle-brachial index; ACS, acute coronary syndrome; BMI, body mass index; cfPWV, carotid-femoral pulse wave velocity; LDL, low-density liproprotein.

or respiratory instability was an exclusion criterion, as seen for instance by the mean systolic blood pressure of 140 mmHg (SD 23.8) and the mean diastolic blood pressure of 86 mmHg (SD 14), as well as only 27 of the 1080 (2.5%) included patients showing hypotension at the time of ABI and PWV measurement.

3.2 | Ankle-brachial index and pulse wave velocity

ABI values were available in all (100%) included patients, and their demographic, clinical and laboratory data are shown in Table 1. Cf-PWV values were available in 1028 of 1080 included patients (95.2%), and their data are listed in Table 2.

3.3 | Mortality

Over a median time of follow-up of 24.4 months (IQR 18.7–31.3), 112 deaths (10.4%, n=112/1080) were recorded. The mean age at time of death was 72.2 ± 14.1 years (women: 73.4 ± 15.9 years; men: 71.3 ± 12.8 years). The mean time between measurements of ABI and cfPWV at the ED and death was 10.1 (SD 10.1) months. Most patients died due to progression of a malignant disease (2.1%), followed by infection (1.9%; in detail: pneumonia .8%, COVID-19 1% and urinary tract infection .1%). Fifteen patients died of a cardiac cause (1.4%; in detail: .8% acute coronary syndrome and .6% cardiac decompensation). Two patients died from bleeding (2%; gastrointestinal or intracranial). In 50 cases (4.6%), no clear cause of death could be determined (mostly due to loss to

^aPreviously known from medical records.

TABLE 2 Demographic and clinical characteristics of 1028 acutely ill medical patients with carotid-femoral pulse wave velocity measurements.

	Study population	cfPWV < 10.0 m/s	$cfPWV\!\geq\!10.0m/s$	
Category	n = 1028 (100%)	n=567 (55%)	n=461 (45%)	<i>p</i> -Value
Age [years]	58.8 ± 17.3	50.3 ± 15.8	69.2 ± 13.0	<.001
Female sex	452 (44.0)	247 (43.6)	205 (44.5)	.80
BMI [kg/m ²]	27.4 ± 5.6	27.6 ± 5.9	27.3 ± 5.1	.95
Comorbidities				
Arterial hypertension	512 (49.8)	207 (36.5)	305 (66.2)	<.001
Dyslipidemia	300 (29.2)	126 (22.2)	174 (37.7)	<.001
Diabetes mellitus type 2	182 (17.7)	54 (9.5)	128 (27.8)	<.001
Chronic kidney disease	79 (7.7)	22 (3.9)	57 (12.4)	<.001
Peripheral arterial disease ^a	37 (3.6)	8 (1.4)	29 (6.3)	<.001
Cerebrovascular disease	42 (4.1)	10 (1.8)	32 (6.9)	<.001
Previous stroke	48 (4.7)	13 (2.3)	35 (7.6)	<.001
Atrial fibrillation	129 (12.5)	46 (8.1)	83 (18.0)	<.001
Coronary artery disease	183 (17.8)	69 (12.2)	114 (24.7)	<.001
Previous ACS	152 (14.8)	65 (11.5)	87 (18.9)	<.001
Ever smoker	354 (34.4)	211 (37.2)	143 (31.0)	.09
Laboratory data				
Triglycerides [mg/dL]	139 ± 109	134 ± 104	145 ± 115	.014
LDL-cholesterol [mg/dL]	101 ± 45	98 ± 41	103 ± 50	.580
Lipoprotein(a) [mg/dL]	52 ± 69	57 ± 74	47 ± 61	.546
Vascular hemodynamics				
cfPWV [m/s]	10.1 ± 2.9	8.0 ± 1.2	12.6 ± 2.3	-
ABI	$1.1 \pm .11$	$1.1 \pm .1$	$1.0 \pm .1$	<.001

Note: Categorial data are presented as counts and percentages, continuous data as means and standard deviations.

Abbreviations: ABI, ankle-brachial index; ACS, acute coronary syndrome; BMI, body mass index; cfPWV, carotid-femoral pulse wave velocity; LDL, lowdensity liproprotein.

follow-up). 30-day mortality was 4.9% in patients with a pathological ABI, and 1.4% with a normal ABI (log-rank p = .003). There was also a significant difference over the entire observational period regarding cumulative mortality (log-rank p < .001; Figure 1A). Thirty-day mortality was 2.4% in patients with cfPWV ≥10 m/s and .7% in patients with cfPWV <10 m/s (log-rank p = .025; Figure 2), and cumulative mortality over the whole period differed between a cfPWV \geq 10 m/s and <10 m/s as well (p<.001; Figure 1B).

3.4 Co-prevalence of risk factors

Within the spectrum of cardiovascular risk factors, the patients' age and the presence of chronic kidney disease were the only two variables independently associated with mortality in addition to ABI and cfPWV (patients' age: HR 1.06 [95% CI 1.04-1.08], p<.001; chronic kidney disease: HR 4.52 [95% CI 2.75–7.44], p<.001). After adjustment for patients' age and the presence of chronic kidney disease in a multivariate model, both ABI and cfPWV remained significantly related to mortality (ABI: HR .12 [95% CI .02-.96], *p* < .001, cfPWV: HR 1.07 [95% CI 1.02–1.21], p < .001). After involving demographic and clinical parameters which differed between individual ABI- and cfPWV categories, the association between ABI and cfPWV and mortality remained statistically significant. After adjustment for all cardiovascular risk factors (see Section 2) in a multivariate model, both ABI and cfPWV were not significantly related to patients' mortality anymore. Neither body mass index nor smoking status differed between the respective ABI- or cfPWVcategories (Tables 1 and 2).

^aPreviously known from medical records.

(A) Long-term mortality - ABI

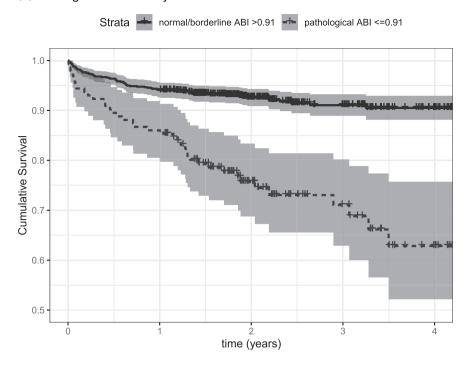
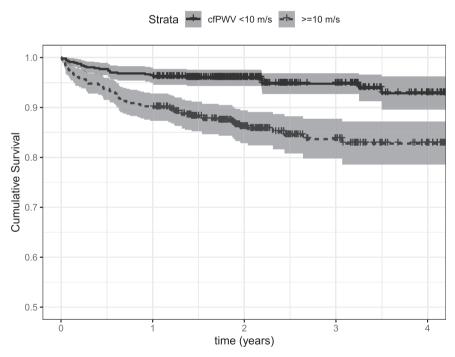


FIGURE 1 (A)+(B) Kaplan Meier curves showing the cumulative probability of survival in acutely ill medical patients. The curves are categorized (A) by their ankle brachial index (ABI; normal/borderline ABI > .91 vs. pathological ABI \leq .91), and (B) by their carotid-femoral pulse wave velocity (cfPWV \leq 10 m/s vs. \geq 10 m/s).

(B) Long-term mortality - cfPWV



4 | DISCUSSION

This study demonstrates the independent prognostic value of ABI and cf-PWV on short- and long-term all-cause mortality in acutely ill medical patients.

In the busy real-time setting of overcrowded EDs with a heterogenous patient population, immediate and rapid risk assessment is crucial. Aiming at risk stratification of acutely ill patients, the major strengths of ABI-, as well as of cf-PWV-measurements, are their easy applicability, quick learnability, short examination time, low costs and noninvasive character. Previously, we could demonstrate the feasibility and prognostic value of an oscillometric vascular assessment in a selected sample of patients presenting with an acute medical condition due to a coronavirus 2019 infection. Also, we showed that PWV has specific prognostic value in acute coronary syndrome and coronary intervention. Apart from proving feasibility of

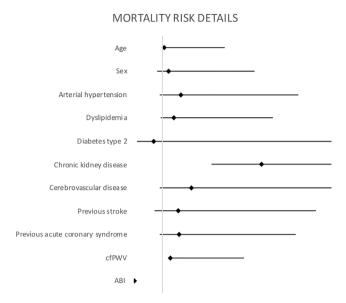


FIGURE 2 Mortality risk details. Forest plot depicting the hazard ratios and 95% confidence intervals for patients' mortality risk of ankle brachial index (ABI) and carotid-femoral pulse wave velocity (cfPWV) including individual comorbidities, demographic variables and cardiovascular risk factors.

these measurements in emergency medicine, these observations led us to the idea of systematically investigating the value of ABI and cf-PWV within the initial triage assessment for risk stratification at the ED. In the current study, we once again observed excellent feasibility of ABI PWV measurements.

In our heterogenous patient collective, a pre-existing diagnosis of peripheral arterial disease was known in 3%–4%. This recording contrasts with the substantially higher proportion of patients with low ABI measurements in the study population (13.2% of patients with ABI <.9), indicating a correspondingly higher prevalence of peripheral arterial disease. Against the background of previously published epidemiological data, and taking the mean age of included patients into account, the proportion of patients with low ABI measurements may probably be more exact than medical history. 16,17 This discrepancy is most likely attributable to a high proportion of asymptomatic patients with peripheral arterial disease and to a still existing lack of awareness, resulting in an underestimation of disease prevalence in the general population. 18,19 Regarding underlying peripheral arterial disease, it has been shown that cardiovascular risk is increased in asymptomatic as well as in symptomatic patients. 20,21 Importantly, the impact of a (potentially yet unknown) pathological ABI on mortality risk could already be observed within the first 30 days after patients' ED presentation. The prognostic significance of the ABI on short-term survival underlines its value as clinical decision support tool within the triage process in the acute

setting. In addition, the association between a reduced ABI and long-term survival allows for an identification of individuals being at increased cardiovascular risk and who would be likely to benefit from specific further patient and resource allocation, diagnostics, referral and follow-up.

While the ABI primarily reflects peripheral arterial perfusion which may be impaired by peripheral atherosclerosis, cfPWV is commonly regarded as marker of central arterial stiffness affected by arteriosclerosis. In contrast to atherosclerosis within the perturbed endothelium, arteriosclerosis can be attributed to an elastic remodelling process occurring on the level of the arterial media due to the loss of elastic fibres and increased fibrosis, thus causing arterial stiffness.^{7,22} Within the spectrum of risk factors potentially contributing to the loss of arterial wall elasticity, patients' age and the presence of arterial hypertension are regarded as key players contributing to arterial stiffness and increased cfPWV. Accordingly, in the present investigation, patients with a cfPWV≥10 m/s were significantly older than the group of patients with cfPWV<10 m/s. In addition to the distribution of patients' age and arterial hypertension, other cardiovascular risk factors and clinical manifestations of atherosclerosis, as well, were more prevalent in patients with a cfPWV≥10 m/s. Interestingly, smoking status was equally distributed between patients with a cfPWV≥10 m/s and <10 m/s. This might be explained by the cumulation of active and previous smokers in one variable in this study.

By analogy with the demographic profile of patients with an increased cfPWV, the prevalence of cardiovascular risk factors and patients age were both increased in patients with a low ABI. It thereby becomes clear that an increased cfPWV and a low ABI, as well, characterize a vulnerable group of acutely ill medical patients with a severe cardiovascular risk profile. Importantly, the multivariate analysis demonstrated that—in addition to patients' age and the presence of chronic kidney disease—both measures, ABI and cfPWV, independently predict shortand long-term mortality.

An increased cfPWV and low ABI characterize a vulnerable group of acutely ill medical patients with a severe cardiovascular risk profile, confirmed by multivariate analysis. Patients being evaluated for their vascular status and function as part of the initial triage assessment and showing pathological values can thus be seen as a proxy of a sicker cohort with an overall worse cardiovascular situation. We have previously described pathological PWV as a triage tool and a surrogate for polyvascular disease and a large atherosclerotic burden. Now adding the value of short-term mortality prediction with possible impact on further decision-making and follow-ups as described

above, this approach seems highly valuable. Naturally, further research must be conducted on this topic before routine implementation into emergency department workflows.

5 | LIMITATIONS

Our study was conducted on a single center basis, rendering a clinical practice bias possible, with special regard to the tertiary and academic setting. However, due to our center's wide and—regarding emergency medicine, unselected—catchment conditions, a sufficient patient heterogeneity can be assumed. Moreover, several methods for ABI and PWV assessment are known, each with their individual advantages and disadvantages, and various approaches might differ in precision. 4,23 Aiming at improving feasibility and aiming at ensuring timely measurements in the emergency setting, we implemented an automated oscillometric device for the automated determination of ABI and cfPWV in the present study. Also, we previously reported an acceptable respective reproducibility and feasibility. 8,9 Of note, when adjusting for all assessed cardiovascular risk factors (not just those showing significant associations individually), ABI and PWV were not significantly related to patients' mortality anymore. However, ABI and PWV are naturally linked to the overall cardiovascular situation of a patient. Also, we see the value in ABI or PWV measurements in an ED in its power to make a cumulative cardiovascular statement without having to assess and add all known cardiovascular risk factors.

The major strengths of this study are being the first and, to our knowledge, the only one on a systematic implementation of ABI and cfPWV assessment on triage level at an ED, and the large sample size of acutely ill medical patients.

6 | CONCLUSION

In acutely ill medical patients, the noninvasive ABI and cfPWV assessment at triage level allows for an initial and independent risk stratification in the emergency setting for short- and long-term mortality. Patients with pathological ABI and cfPWV values could thus be seen as a proxy for a sicker cohort with an overall worse polyvascular situation.

AUTHOR CONTRIBUTIONS

SS, JO, and OS were involved in conceptualization and methodology. JO was involved in formal analysis. SS, JO, AK, FE, MN, RB, CV, ND, SW, NG, CG, MM, and HD were

involved in investigation. SS, HD, RK, and OS were involved in resources. SS, JO, FE, MN, AK, RB, CV, ND, SW, NG, and CG were involved in data curation. SS, JO, AK, and OS were involved in writing—original draft. SS, JO, AK, FE, MN, RB, CV, ND, SW, NG, CG, TP, HH, MM, HD, RK, and OS were involved in writing—review and editing. JO and OS were involved in visualization. SS, TP, HH, HD, RK, and OS were involved in project administration.

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CONFLICT OF INTEREST STATEMENT None.

DATA AVAILABILITY STATEMENT

The data underlying this article will be shared on reasonable request to the corresponding author, according to national law.

PATIENT AND PUBLIC INVOLVEMENT STATEMENT

It was not appropriate or possible to involve patients or the public in the design, conduct, reporting or dissemination plans of our research.

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