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Diagnostic value of the modified Duke criteria in suspected infective endocarditis —The PRO-ENDOCARDITIS study

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ABSTRACT

Objectives: To determine whether relevant comorbidities stratify patients with and without IE and whether these may improve the diagnostic accuracy, in addition to the modified Duke criteria.
Methods and Results: 261 consecutive patients (aged 60.1 ± 16.1 years, 62.8% male) with suspected IE were prospectively included in this single-center observational trial. Modified Duke criteria and relevant comorbidities as well as clinical characteristics, were assessed. Forty-seven patients had IE, as confirmed by a clinical event committee. Patients with IE had a higher frequency of positive blood cultures (70.2% vs. 36.9%, $p < 0.0001$), embolic diseases (36.2% vs. 10.8%, $p < 0.0001$), heart murmurs (27.7% vs. 11.7%, $p = 0.01$), and intensive care therapy (74.5% vs. 58.4%, $p = 0.04$). In receiver operating characteristics, the combination of modified Duke criteria without transesophageal echocardiography led to an area under the curve of 0.783 (0.715–0.851). The predictive value was only marginally improved by the addition of heart murmur and intensive care therapy (0.794 [0.724–0.863]). In contrast, transesophageal echocardiography alone achieved an area under the curve of 0.956 (0.937–0.977) and was further improved when adding modified Duke criteria, heart murmur, and intensive care therapy (0.999 [0.998–1.000]).
Conclusion: Modified Duke criteria provide excellent diagnostic value for evaluating suspected IE, mainly driven by transesophageal echocardiography.
Trial registration: NCT03365193.

Introduction

Infective endocarditis (IE) is a potentially lethal disease. Its clinical presentation and etiology have undergone major changes over the last decades (Habib et al., 2019). The Duke criteria and the latest modification are recommended for evaluating the probability of the presence of IE by current guidelines (Habib et al., 2015, Li et al., 2000). However, since the introduction of Duke criteria in 1994 and the current recommendations in 2000 (Durack et al., 1994, Li et al., 2000), characteristics of patients presenting with potential IE have substantially changed, especially in tertiary care facilities, towards a high proportion of patients with immune deficiency (caused by illness or medically induced), critically ill patients, patients with prosthetic valves and patients with long-lasting intensive care treatment (Habib et al., 2019). Likewise, with the increasing interventional therapy of structural heart disease and device implantation in older and multi-morbid patient cohorts, the frequency of endocarditis on prosthetic material and devices has increased over recent decades (Toyoda et al., 2017). While Duke criteria overall misclassify a substantial proportion of patients with endocarditis (Habib et al., 1999), they are challenging to apply to these patients because of lower sensitivity. Therefore, several modifications of the Duke criteria have been proposed (Klug et al., 1997, Sohail et al., 2008). In clinical practice, this uncertainty leads to frequent demands for diagnostic imaging with a high frequency of referrals for transesophageal echocardiography

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for suspected IE, as clinical characteristics describing the pretest-probability before imaging, are lacking. In the present prospective observational study, we aimed (I) to identify whether the characteristics from the modified Duke criteria as well as relevant comorbidities differentiate patients with and without IE, (II) to determine the sensitivity and positive prognostic values of these characteristics, excluding echocardiography, for the detection of confirmed IE and (III) to evaluate the diagnostic value of the Duke criteria and other characteristics in a cohort of patients with suspected IE, treated in a large, university-based tertiary care facility.

Methods

Study sample

Between December 2017 and May 2019, consecutive patients referred to the West German Heart and Vascular Center's echocardiography laboratory for transesophageal echocardiography for suspected IE were prospectively enrolled. Exclusion criteria were preexisting confirmed IE and inability or unwillingness to provide informed consent. Prior to initiation of the study, a sample size of 251 patients was estimated to provide sufficient statistical power (80% power, 5% type I error, probability of IE: 0.3, 10% exclusion for incomplete variables, multivariable regression analysis including up to ten variables). From 261 screened patients, all patients were eligible and willing to participate. Complete information regarding the requested variables was obtained for all patients. The study protocol conforms to the ethical guidelines of the 1975 Declaration of Helsinki as reflected in a priori approval by the institution's human research committee (17-7747-BO). All patients included provided informed consent.

Echocardiography imaging

All transesophageal echocardiography imaging was performed at the West German Heart and Vascular Center's echocardiography laboratory at the University Hospital Essen by dedicated physicians in a standardized manner. Images were acquired using an Epiq 7 C ultrasound system with an X7-2 or X8-2 probe (Philips Healthcare, Amsterdam, the Netherlands). Images were digitally stored and transferred to the center's core laboratory. At the core lab, all images were evaluated with consensus by two board-certified cardiologists, highly experienced in cardiovascular imaging, who were blinded to the clinical presentation and covariate assessment of the patients. Echocardiography was rated as typical IE signs, not typical for IE, and no signs of IE.

Duke criteria and other covariate assessment

After informed consent and before the transesophageal echocardiography examination, all patients underwent structured anamnesis, vital sign assessment, and physical examination for the assessment of modified Duke criteria according to current European Society of Cardiology guidelines (Habib et al., 2015, Li et al., 2000). The following variables were assessed: age, gender, height, current temperature, heart murmur, intravenous drug abuse, Osler nodules, Janeway lesions, petechial bleedings, and current central catheters. From the medical history of the patient, presence of a pacemaker or implanted defibrillators, valve prosthesis or prior valve repair, congenital heart defects, cancer, immunosuppression, intensive care therapy within the last 12 months, recent vascular events (within the last 90 days), and prior transthoracic echocardiography evaluation were assessed. All available hospital records were screened for the most recent white blood cell count, c-reactive protein, and pro-calcitonin for the maximal documented temperature (including the date when observed) and blood cultures, including specification of bacteria. Stratification into typical and atypical microorganisms in the blood cultures was made following current guidelines [2].

Endpoint definition

A clinical endpoint committee of board-certified cardiologists, independent of the study team, adjudicated IE's presence. For this, all available clinical information, including laboratory results, surgery reports, blood culture results, physician notes, pathology reports, discharge letters, and all available imaging, were provided. A decision was made by consensus in all cases. For endpoint decision, clinical characteristics before and after transesophageal echocardiography were included.

Statistical analysis

Continuous variables are reported as mean±standard deviation (SD). Discrete variables are given in frequency and percentiles. Patients' baseline characteristics were stratified by the presence and absence of confirmed IE, as defined by the clinical endpoint committee. Continuous variables were compared using a 2-sided *t-test* or Mann-Whitney-U-test (for non-normal distributed variables) and discrete variables using the 2-sided Fischer's Exact test. Univariate logistic regression analysis was performed to determine the association of single variables from the Duke criteria (bacteriemia fulfilling major criteria, predisposing condition, fever >38 °C, bacteriemia fulfilling minor criteria, embolic disease, dermal vascular phenomena, and positive positron-emission-tomography), intensive care therapy, and a heart murmur. For multivariate regression analysis, all variables from univariate analyses were included. Logistic regression analysis for the association of specific bacteremia species was performed without additional adjustment due to the limited number of individual species cases. Receiver operating characteristic was used to determine the ability to diagnose IE of predefined sets of characteristics as follows: (A) modified Duke characteristics excluding transesophageal echocardiography, (B) modified Duke characteristics excluding transesophageal echocardiography and ancillary heart murmur and intensive care therapy, (C) Transesophageal echocardiography alone, (D) modified Duke characteristics including transesophageal echocardiography, heart murmur, and intensive care therapy. All analyses were performed using SAS software (Version 9.4, SAS Institute Inc.). A p-value of <0.05 indicated statistical significance.

Results

Between December 2017 and April 2019, 261 consecutive patients (mean age 60.1±16.1 years, 62.8% male) with suspected IE were prospectively included in our study. Detailed patient characteristics for the overall cohort and stratified by confirmed IE are depicted in Table 1. Patients with IE were slightly older and had a higher frequency of positive blood cultures, embolic diseases, heart murmurs, and intensive care therapy within the past twelve months. There was a trend towards a higher frequency of dermal vascular phenomena, which did not reach statistical significance. The presence of a central venous catheter, cancer, immunosuppression, and systemic inflammatory markers did not differ between patients with and without confirmed IE. 45 patients (17.2%) received positron emission tomography as part of the clinical workup. From seven patients with positive PET CT/PET MRI findings, only four were adjudicated as having infective endocarditis by the clinical endpoint committee. In contrast, twelve patients without evidence of infective endocarditis on PET were

Table 1
Patients characteristics.

	Overall (n = 261)	No endocarditis (n = 214)	Endocarditis (n = 47)	p-value
Age, years	60.1 ± 16.1	59.3 ± 16.2	63.6 ± 15.6	0.09
Male gender, n (%)	264 (62.8)	133 (62.2)	31 (66.0)	0.74
BMI (kg/m^2)	26.7 ± 5.8	26.4 ± 5.2	28.3 ± 8.2	0.15
Prosthetic valve, n (%)	34 (13.0)	27 (12.6)	7 (15.9)	0.64
Implanted Device, n (%)	27 (10.3)	20 (9.4)	7 (14.9)	0.29
Central venous catheter, n (%)	105 (40.2)	85 (39.7)	20 (42.6)	0.74
Cancer, n (%)	72 (27.6)	62 (29.0)	10 (21.3)	0.37
Positive blood culture, n (%)	112 (42.1)	79 (36.9)	33 (70.2)	<0.0001
Immunosuppression, n (%)	77 (29.5)	67 (31.3)	10 (21.3)	0.22
- Posttransplantation, n (%)	23 (8.8)	20 (9.3)	3 (6.4)	
- Cancer therapy-induced, n (%)	22 (8.4)	17 (7.9)	5 (10.6)	
- Immunodeficiency, n (%)	7 (2.7)	5 (2.3)	2 (4.3)	
- Other	25 (9.6)	25 (11.7)	0	
Heart murmur, n (%)	38 (14.6)	25 (11.7)	13 (27.7)	0.01
Fewer >38 °C, n (%)	144 (55.2)	118 (55.1)	26 (55.3)	1.0
Intensive care therapy, n (%)	77 (29.5) 83 (31.8)	64 (29.9) 61 (28.5)	13 (27.7) 22 (46.8)	0.04
- Currently				
- Within the past 12 months				
Congenital heart defect, n (%)	9 (3.5)	6 (2.8)	3 (6.4)	0.21
Injection drug abuse, n (%)	6 (2.3)	4 (1.9)	2 (4.3)	0.30
Embolic disease, n (%)	40 (15.3)	23 (10.8)	17 (36.2)	<0.0001
Dermal vascular phenomena, n (%)	13 (5.0)	8 (3.7)	5 (10.6)	0.06
Positron emission tomography	45 (17.2) 7 (2.7)	33 (15.4) 3 (1.4)	12 (25.5) 4 (8.5)	0.069
- performed				
- positive, n (%)				
White blood cell count, /nl	9.8 ± 6.7	9.8 ± 6.8	10.0 ± 5.9	0.80
C-reactive protein, mg/dl	8.6 ± 8.2	8.2 ± 8.0	10.5 ± 8.9	0.09

adjudicated as infective endocarditis positive after reviewing the patient's full clinical information (Table 1). In the univariate regression analysis, typical and atypical microorganisms in blood culture, predisposing condition, embolic diseases, intensive care therapy, and heart murmur were associated with confirmed IE (Table 2). In the multivariate analysis, effect sizes remained stable for all variables except for intensive care therapy, while the association of heart murmur did not reach statistical significance in the multivariate model. This was predominantly caused by a higher frequency of detection of typical and atypical microorganisms, fever >38 °C, and embolic disease in intensive care therapy (Supplementary Table 1).

Stratifying by pathogens detected within the blood cultures, we observed comparable effect sizes for all detected species (Supplementary Fig. 1). The odds ratio for the association of Staphylococcus aureus bacteremia with confirmed IE was comparable to other Staphylococcus species and Candida but slightly higher for the Streptococcus species.

Sensitivity and positive predictive value of Duke-criteria for the detection of IE without transesophageal echocardiography

We evaluated the sensitivity and positive predictive value of each parameter from modified Duke-criteria (excluding transesophageal echocardiography) for the detection of IE, to detect parameters that may qualify to increase the pretest-probability before transesophageal echocardiography. We observed that sensitivity was highest for patients with fever >38°, while a positive predictive value was highest for positive blood culture, graded as minor criteria according to Duke criteria (Supplementary Table 2). Further evaluating intensive care therapy and heart murmur, we observed high sensitivity for patients treated on

Table 2
Univariate and multivariate logistic regression analyses for the association of characteristics from the modified Duke criteria excluding echocardiography and heart murmur as well as intensive care therapy with confirmed infective endocarditis.

	Univariate		Multivariate	
	OR (95% CI)	p-value	OR (95% CI)	p-value
Typical microorganisms[a]	2.66 (1.40–5.06)	0.003	5.18 (2.21–12.8)	0.0002
Predisposing condition[b]	2.09 (1.07–4.08)	0.03	2.27 (1.05–4.91)	0.03
Fever >38 °C	1.01 (0.53–1.91)	0.98	1.16 (0.55–2.46)	0.70
Atypical microorganisms[c]	4.13 (1.20–14.15)	0.02	6.17 (1.36–28.0)	0.01
Embolic disease	4.71 (2.26–9.82)	<0.0001	7.55 (3.02–18.9)	<0.0001
Dermal vascular phenomena	3.07 (0.96–9.83)	0.06	2.39 (0.57–9.97)	0.23
PET****	5.00 (0.93–27.04)	0.06	4.34 (0.42–4.37)	0.22
Intensive care therapy	2.08 (1.02–4.22)	0.04	1.20 (0.53–2.70)	0.66
Heart murmur	2.89 (1.35–6.20)	0.006	2.11 (0.89–4.99)	0.09

[a] according to DUKE-major criteria, adopted from Li et al. (2000).
[b] predisposing condition: valve prosthesis, device, congenital heart defect, or injection drug abuse.
[c] according to DUKE-minor criteria, adopted from Li et al. (2000).

Table 3
Receiver operating characteristics for the predictive value of modified Duke-Criteria variables with and without transesophageal echocardiography.

Variable	ROC (95% CI)
Duke criteria excluding echocardiography	0.783 (0.715–0.851)
Duke criteria excluding echocardiography+heart murmur+intensive care	0.794 (0.724–0.863)
Transesophageal echocardiography	0.956 (0.937–0.977)
Duke criteria including transesophageal echocardiography+heart murmur+intensive care	0.999 (0.998–1.000)

intensive care units, while moderate sensitivity and a positive predictive value was observed for heart murmur. In receiver operating characteristics, combining the Duke criteria without echocardiography led to an area under the curve of 0.783 (Table 3, Figure 1). The predictive value was only marginally and not significantly improved by adding heart murmur and intensive care therapy as parameters. In contrast, transesophageal echocardiography alone achieved an area under the curve of 0.956 and was further improved when adding the information of Duke criteria, heart murmur, and intensive care therapy.

Discussion

In this prospective observational study, we found that characteristics of the modified Duke criteria stratified patients with vs. without IE. Also, heart murmur and intensive care therapy were associated with IE, while relevant comorbidities such as cancer, immunosuppression, central venous catheter, or systemic inflammatory markers did not differ between patients with and without confirmed IE. Further, we observed that bacteremia fulfilling major criteria according to Duke criteria neither provided higher positive predictive value nor stronger associations with IE compared to detection of pathogens, considered as minor criteria according to Duke. Therefore, our results do not support maintaining the stratification into typical and atypical infective pathogens for this purpose. Transesophageal echocardiography outperformed all other clinical characteristics regarding confirmation and ruling out of suspected IE in our study, suggesting that transesophageal echocardiography should be performed

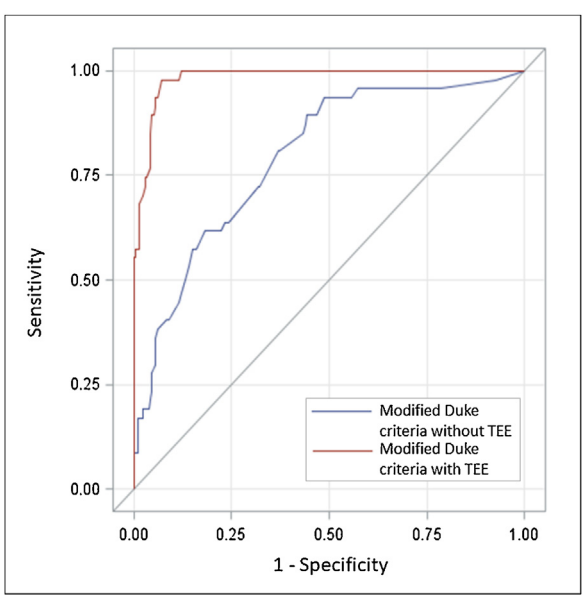

Figure 1. Receiver operating characteristics for the predictive value of modified Duke criteria without transesophageal echocardiography (blue) and with transesophageal echocardiography (red).

whenever IE is suspected. Ultimately, our study confirms that even in modern tertiary care settings with high proportions of patients with relevant comorbidities, the modified Duke criteria provide excellent diagnostic value in patients with suspected IE.

Echocardiography is a critical diagnostic test for evaluating suspected IE according to Duke criteria and current guidelines (Habib et al., 2010, Habib et al., 2015, Nishimura et al., 2017). While the diagnostic accuracy of transesophageal echocardiography is high, the sensitivity of transthoracic echocardiography ranges only around 50%, especially in the case of prosthetic valves (Habib et al., 2010, Mugge et al., 1989). With advances in the image quality of transesophageal echocardiography and the broad availability of ultrasound systems capable of providing 3-dimensional visualization, its diagnostic value has further increased also in challenging cases (Berdejo et al., 2014, Liu et al., 2009). This is confirmed by our analysis, as we observed a very high predictive value of transesophageal echocardiography for detection of IE, when routinely utilizing 3-dimensional techniques.

With advances in multi-modality imaging, diagnostic approaches are currently adapting and will further improve imaging technologies and new applications. For instance, a recent prospective evaluation from three French centers found that ^{18}F-FDG-positron emission tomography combined with computed tomography may be a useful tool in suspected IE, improving the sensitivity of diagnostic algorithms (Philip et al., 2020). In our observational study, positron emission tomography was performed in 18% of patients and improved the model's accuracy. However, when compared to transesophageal echocardiography, it provided relevantly lower improvement in receiver operating characteristics. Therefore, our data support the outstanding role of transesophageal echocardiography in diagnostic algorithms in patients with suspected IE. In contrast, positron emission tomography is currently reserved for challenging IE scenarios with prosthetic valves or cardiac implantable electronic devices (Wang et al., 2020).

Besides confirmed IE from histopathological evaluation after surgery, in clinical routines IE diagnosis usually relies on clinical characteristics suggestive of IE. The Duke criteria from 1994 and their modification in 2000 (Durack et al., 1994, Li et al., 2000) are used as critical diagnostic algorithms with a sensitivity of approximately 80%, as described in the literature (Habib et al., 1999, Hill et al., 2007, Vieira et al., 2004). In selective cohorts such as endocarditis on prosthetic valves or cardiac devices, diagnostic accuracy may be even lower (Hill et al., 2007, Vieira et al., 2004). Existing literature suggests that advances in imaging technologies have the highest probability of improving diagnostic algorithms' sensitivity (Bruun et al., 2014, Fagman et al., 2012, Feuchtner et al., 2009, Thuny et al., 2013). Using 3-dimensional transesophageal echocardiography on modern ultrasound machines, we achieved excellent diagnostic accuracy, suggesting that recent improvements in image quality in transesophageal echocardiography have further strengthened its role in the workup of patients with suspected IE.

Clinical implications

Despite establishing Duke criteria 30 years ago, its usage today still provides excellent diagnostic performance in patients with suspected IE. However, our results in a patient cohort from a large tertiary care facility suggest that stratification according to infective pathogens (according to Duke's minor and major criteria) is not associated with IE's divergent risk. Moreover, the present study underlines the vital role of transesophageal echocardiography in patients with suspected IE. With modern echocardiography equipment in experienced centers, transesophageal echocardiography provides better identification of endocarditis than the

combination of remaining Duke criteria and, therefore, should be performed as the number one test for diagnosis of potential IE.

Limitations

Our study is limited by the single-center study design with a patient cohort different from other centers. However, our cohort reflects a high frequency of patients after organ transplantation with immunosuppression, in an intensive care unit, or otherwise severely diseased patients, which may reflect a growing challenge in modern medicine. Besides, the frequency of confirmed IE was lower than anticipated when designing the study. Still, we observed sufficient statistical power to execute all predefined analyses.

Conclusion

Modified Duke criteria, as suggested by current guidelines, provide excellent diagnostic value for the evaluation of suspected IE in severely diseased cohorts as routinely present in tertiary care centers, mainly driven by transesophageal echocardiography. In contrast, relevant comorbidities such as immunosuppression or cancer were not linked with increased IE probability. Whenever IE is suspected, transesophageal echocardiography should be performed with priority.

Declarations of interest

None declared.

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Authorship contributions

Amir A. Mahabadi: Conception or design of the work, substantial contributions to the acquisition, analysis and interpretation of data for the work, drafting the manuscript. Final approval of the version to be published. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Ihab Mahmoud: Substantial contributions to the acquisition and analysis, revising the manuscript critically for important intellectual content. Final approval of the version to be published.

Iryna Dykun: Substantial contributions to the analysis and interpretation of the work, revising the manuscript critically for important intellectual content. Final approval of the version to be published.

Matthias Totzeck: Substantial contributions to the analysis and interpretation of the work, revising the manuscript critically for important intellectual content. Final approval of the version to be published.

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Tienush Rassaf: Conception or design of the work, substantial contributions to the acquisition, analysis and interpretation of data for the work, drafting the manuscript. Final approval of the version to be published. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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The authors included in the manuscript meet all of the following conditions: 1) substantial contributions to the conception and design, acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content, and 3) final approval of the version to be published.

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

Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.ijid.2021.01.046.

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