What do we mean by complex percutaneous coronary intervention? An assessment of agreement amongst interventional cardiologists for defining complexity

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What do we mean by complex percutaneous coronary intervention? An assessment of agreement amongst interventional cardiologists for defining complexity

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Abstract

Background: In the last decade, percutaneous coronary intervention (PCI) has evolved toward the treatment of complex disease in patients with multiple comorbidities. Whilst there are several definitions of complexity, it is unclear whether there is agreement between cardiologists in classifying complexity of cases. Inconsistent identification of complex PCI can lead to significant variation in clinical decision-making.

Aim: This study aimed to determine the inter-rater agreement in rating the complexity and risk of PCI procedures.

Method: An online survey was designed and disseminated amongst interventional cardiologists by the European Association of Percutaneous Cardiovascular Intervention (EAPCI) board. The survey presented four patient vignettes, with study participants assessing these cases to classify their complexity.

Results: From 215 respondents, there was poor inter-rater agreement in classifying the complexity level ($k = 0.1$) and a fair agreement ($k = 0.31$) in classifying the risk level. The experience level of participants did not show any significant impact on the inter-rater agreement of rating the complexity level and the risk level. There was good level of agreement between participants in terms of rating 26 factors for classifying complex PCI. The top five factors were (1) impaired left ventricular function, (2) concomitant severe aortic stenosis, (3) last remaining vessel PCI, (4) requirement fort calcium modification and (5) significant renal impairment.

Conclusion: Agreement among cardiologists in classifying complexity of PCI is poor, which may lead to suboptimal clinical decision-making, procedural planning as well

as long-term management. Consensus is needed to define complex PCI, and this requires clear criteria incorporating both lesion and patient characteristics.

KEYWORDS
complex percutaneous coronary intervention

1 | INTRODUCTION

Percutaneous coronary intervention (PCI) is the commonest means of coronary revascularization of acute and chronic coronary syndromes.[1,2] In the last decade PCI has evolved considerably toward the treatment of more complex disease in patients with multiple comorbidities. Evidence from studies of PCI in unprotected left main intervention, rotational atherectomy and chronic total occlusion (CTO) has led to an expansion of PCI in these categories.[3,4] Complex PCI[5,6] accounts for almost 40% of cases driven by an increasingly old population who are frequently turned down for bypass surgery by virtue of age and comorbidity.[3] With increasing co-morbidity and complexity comes increased risk.

The importance of an agreed consensus on the definition of complexity of PCI is multi-fold. First, a clear definition is vital in is shaping international guidelines looking at best practice in complex coronary artery disease. A key example is the emerging need to personalize patients' antiplatelet regimes and duration according to the procedure complexity. Indeed, this forms a central part of both ESC (European Society of Cardiology) and ACC (American College of Cardiology)/AHA (American Heart Association) recommendations[7,8] for both acute and chronic coronary syndromes. Complexity has been defined[9] by multiple means including anatomical distribution of disease such as the SYNTAX Score, clinical and procedural characteristics and PCI characteristics,[10] Nevertheless, despite these scoring systems to define complexity, it is unclear whether interventional cardiologists agree on what is meant by complex and high-risk PCI (CHIP). Inconsistent identification of complex PCI cases amongst interventional cardiologists can potentially lead to significant variation in the implementation of guideline recommended care.

This study therefore aimed to: (1) analyze the views of cardiologists on classifying complexity and risk in PCI procedures, (2) determine the inter-rater agreement and variability of rating the complexity and risk of PCI procedures, (3) study the differences in rating PCI procedure complexity amongst cardiologists with varied experiences, and finally (4) determine the factors that are perceived as being important for classifying the complexity of PCI procedures.

2 | METHODS

2.1 | Data collection/survey design

A total of four patient vignettes comprising of coronary angiography images and clinical histories from each patient (see Figures 1 and 2) were presented online (in the form of an anonymous online survey). Participants were asked to rate the complexity and the level of risk for each of these cases. The objectives were to evaluate their interpretation of what they consider to be complex and what they would consider to be high risk characteristics. The survey also comprised of questions to ascertain operator experience and demographics. In addition, the survey asked the participants to rate how important they believed a series of factors were for assessing the complexity and perceived risk of a PCI procedure. The online study can be found on the following link (European Association of Percutaneous Cardiovascular Intervention [EAPCI]—CHIP-PCI Survey [research.net]).

2.2 | Recruitment

The survey was disseminated by the EAPCI board in a mailing list of approximately 60,000 members.

2.3 | Data analysis

The data was analyzed using R programming language and R Studio. Kappa statistics and percentage of agreement were used to study inter-rater agreement and intergroup agreement for classifying complexity level, risk level and factors importance. Pearson's χ^2 test was used to study the association between complexity ratings/risk ratings. Spearman and Pearson correlation coefficients were used to study the correlation between several variables including (1) the number of years of post-fellowship experience, (2) age, (3) gender, (4) volume of procedures undertaken, (5) occupation and (6) country of practice. Boxplots were used to show the variation between the participants' ratings for case complexity and risk for each scenario. Complexity scores (complexity rating + risk rating) for each participant were also analyzed in each scenario. Histograms were used to show the distribution of the variables. Analysis of variance (ANOVA) was used to assess whether there were significant differences between Complexity scores from each of the scenarios.

3 | RESULTS

3.1 | Participant demographics

A total of 272 people responded to the online survey, with 98% identified as interventional cardiologists. Incomplete surveys containing key missing responses (for instance regarding complexity and risk)

were removed from the final data set, resulting in a final number of 215 respondents. The participants ($n = 215$ [males $n = 170$, females $n = 31$, missing data such as gender $n = 14$]) were recruited from 65 countries. The mean age of the participants was 49.4 ± 8.6 years and the mean level of interventional experience was 14.7 ± 8.3 years.

The mean number of PCIs undertaken per year was 1218 ± 851 per institution and 250 ± 150 per operator. Radial access was preferred in 94.8% of cases. Among the respondents left main PCI activity was common with 94.8% performing this procedure. Rotational atherectomy was performed by 79.1% of the respondents with 87.8% performing anterograde wire escalation CTO techniques. Those performing retrograde CTO were lower at 40.2% but still indicative of an experienced group. Overall, this suggested that the sample were representative of those that perform complex PCI.

Approximately one-third of the respondents felt that all interventional cardiologists should perform complex PCI whereas 49.5% of the respondents disagreed with this, suggesting that complex PCI should not be performed by all interventional cardiologists but by "complex operators." While the vast majority of respondents felt that assessing complexity is important (95.1%), only 55% felt that assessment of procedural complexity and risk to the patient was done well in their institution. Interestingly, the vast majority (87%) of the respondents felt that complex PCI should be performed with two operators present.

When questioned about factors related to procedural complexity, there was variation in the opinions in terms of which factors were important or not. However there seemed to be general agreement that the most important factors to consider were vessel tortuosity, requirement for calcium modification and the presence of a CTO. Approximately two thirds of respondents felt that left main PCI should be considered along with 3-vessel PCI and requirement for a 2-stent bifurcation technique. Just over half of the respondents felt that severe concomitant mitral regurgitation, and a predicted stent length of over 60 mm were important. The need for femoral access was generally felt to be unimportant with only 29% considering this important.

3.2 | Inter-rater agreement for rating complexity and level of risk

The participants were divided into six groups based on their experience level (the number of years postfellowship experience) (Table 1).

In each group, the participants rated complexity and risk differently in each scenario (as shown in Figure 1 in the Supporting Information Materials). In terms of inter-rater agreement, there was poor consensus between participants (k = 0.1, Cohen's Kappa) in classifying complexity, while there was fair agreement between participants (k = 0.3, Cohen's Kappa) in terms of classifying risk in each scenario as shown in Figures 3A,B, respectively. Moreover, inter-rater agreement in each group ranged from poor to fair in classifying complexity, and the inter-rater agreement in classifying risk level ranged from fair to moderate in each group (Figures 3C,D).

The percentage of agreement in classifying complexity and risk in the six groups has been computed using the majority/popularity voting in each (Figures 3E,F) as Cohen's kappa can be affected by variation. As shown in Figure 1 in the Supporting Information Materials and Figure 3, scenario 2 and scenario 4 have the lowest agreement values in classifying complexity (−0.05 in scenario 1 and −0.04 in scenario 2) and risk (−0.01 in scenario 1 and −0.01 in scenario 2). The majority of the participants (>50%) rated complexity and risk equally in all scenarios, while the minority rated complexity higher than risk or risk higher than complexity (Table 2). There was a significant association found between risk level and complexity level ($p < 0.001$, Pearson's Chi-squared test) in each scenario.

Experience level did not appear to demonstrate any significant correlation with the classification of complexity and risk. However, group 3 showed slightly higher agreement compared to the other groups in classifying complexity (Figure 3C). In light of this, further analysis was carried out to understand why group 3 has a slightly higher agreement compared to the other groups. It was found that group 3 performed a higher number of PCIs procedures per year (mean=301 ± 237) compared to the other groups (Figure 4). The Complexity score was computed for each scenario using equation 1. Complexity and risk were given ratings from one to five, based on the complexity and risk level (e.g., complexity was rated as being equal to 5 if the complexity level was very high and 1 if the complexity level was not complex at all; with the same method being used for risk rating).

Significant differences were found between the four scenarios in terms of Complexity scores ($p < 0.001$, ANOVA). The median Complexity score value was higher in the first and third scenarios, when compared to the other scenarios (Figure 5), with most participants rating the complexity/

TABLE 1 Participants groups based on the number of years postfellowship experience.

	Group 1 ($n = 28$)	Group 2 ($n = 45$)	Group 3 ($n = 45$)	Group 4 ($n = 35$)	Group 5 ($n = 26$)	Group 6 ($n = 21$)
Level of experience	<5 years	5–10 years	10–15 years	15–20 years	20–25 years	>25 years
Age	40.4 ± 8.1	44.6 ± 4.7	47.1 ± 4.1	52.7 ± 5.8	57.5 ± 5.9	61.5 ± 5.5
Male *n* (%)	22 (78.5%)	38 (84.4%)	38 (84.4%)	27 (77.1%)	23 (88.4%)	18 (85.7%)

rating in those scenarios (scenario 1 and 3) as being higher, as shown in Figure 1 (in the Supporting Information Materials). Furthermore, there was significant variation in terms of Complexity scores between participants in the fourth scenario ($p < 0.05$, ANOVA).

3.3 | Factors for judging complexity and level of risk

The participants were asked to rate 26 factors that could be used for classifying complex PCI procedures. The majority of participants

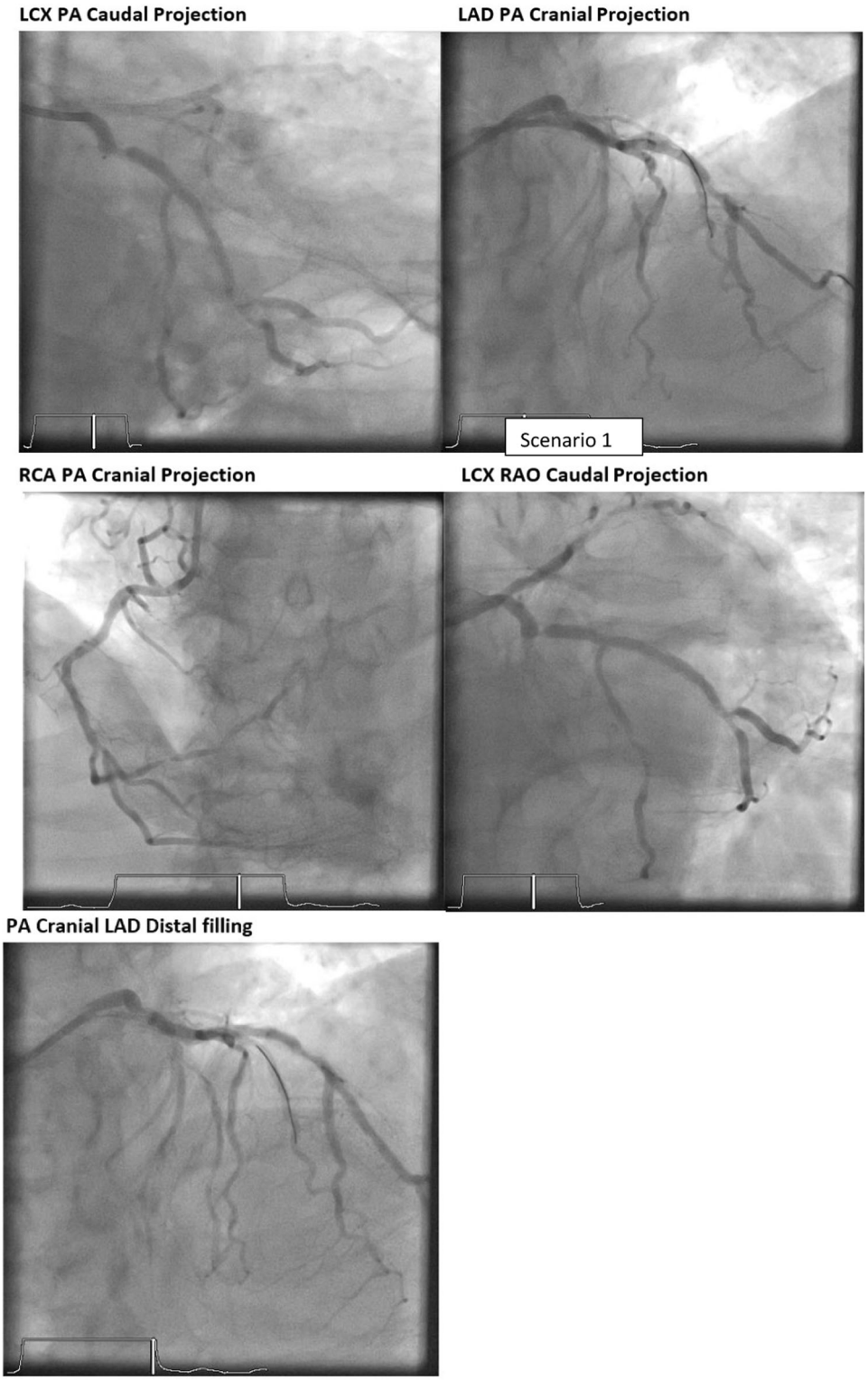

FIGURE 1 Patient angiographic vignettes: Scenario 1 and 2.

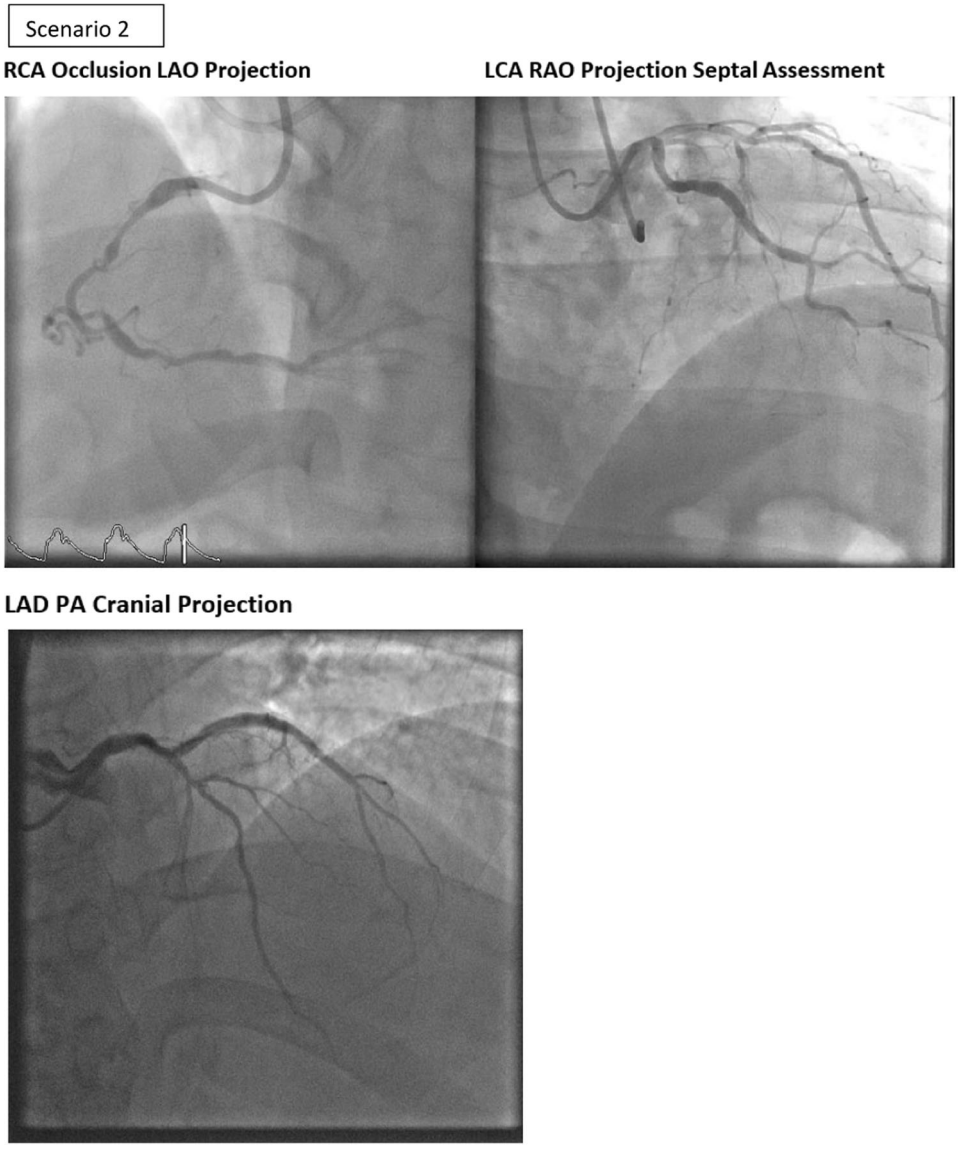

FIGURE 1 Continued

TABLE 2 Frequency of rating complexity higher than risk and vice versa in each scenario.

	Rated complexity higher than risk	Rated risk higher than complexity	Rated complexity and risk equally
Scenario 1	14.4% (*n* = 30)	31.2% (*n* = 65)	54.3% (*n* = 113)
Scenario 2	32.7% (*n* = 68)	10.0% (*n* = 21)	57.2% (*n* = 119)
Scenario 3	4.3% (*n* = 9)	42.3% (*n* = 88)	53.4% (*n* = 111)
Scenario 4	36.5% (*n* = 76)	12.0% (*n* = 25)	51.4% (*n* = 107)

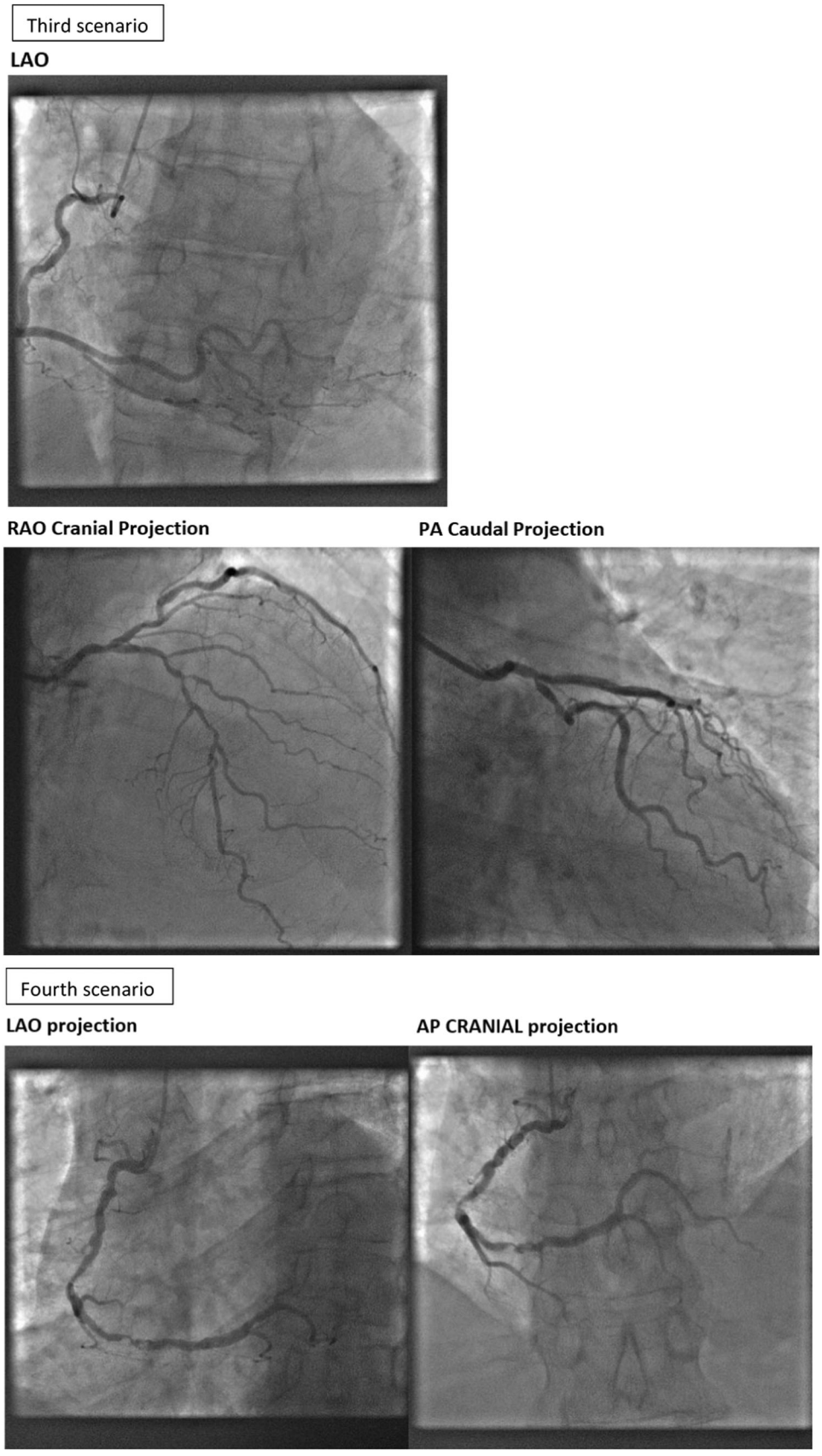

FIGURE 2 Patient angiographic vignettes: Scenario 3 and 4.

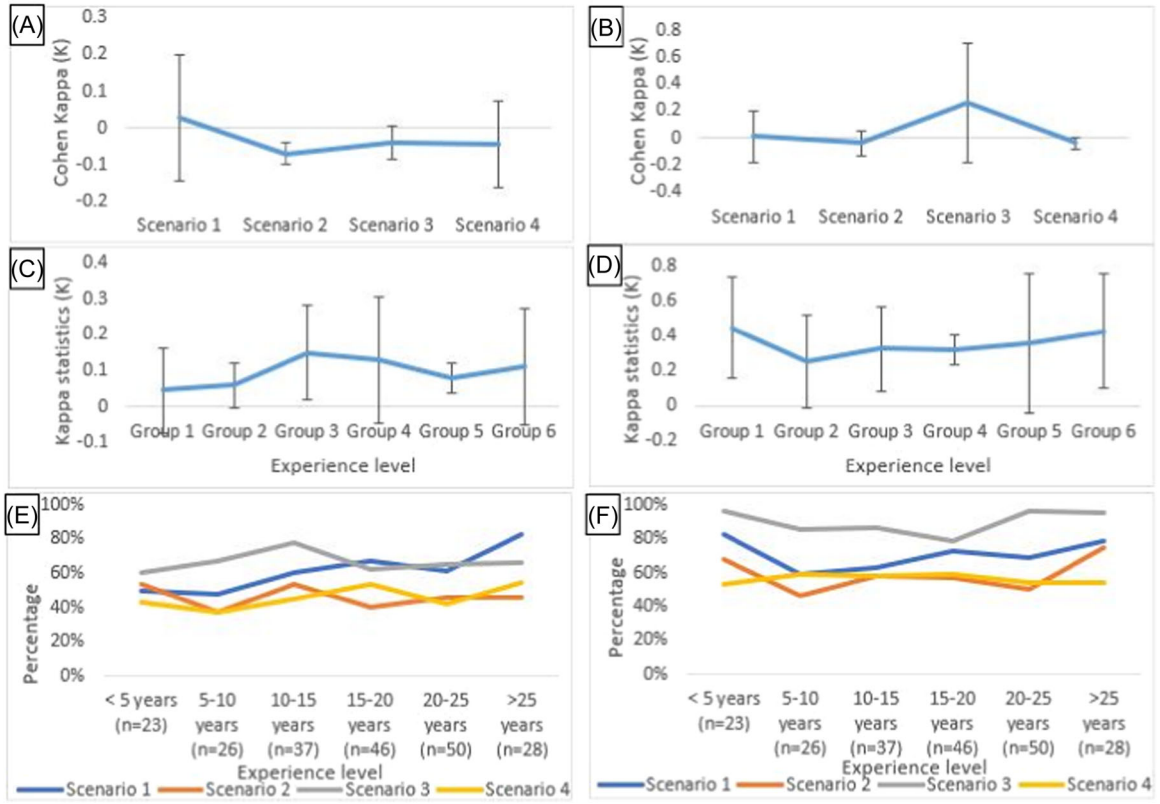

FIGURE 3 Agreement between participants. (A) and (B) represent agreement in classifying complexity and risk respectively between participants in each scenario. (C) and (D) represent agreement in each group in classifying complexity and risk respectively. (E) and (F) represent percentage of agreement in each group in classifying complexity and risk respectively. [Color figure can be viewed at wileyonlinelibrary.com]

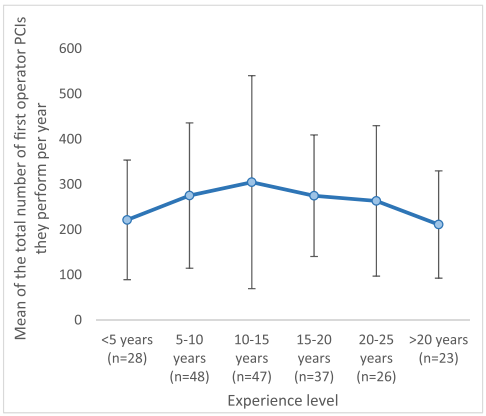

FIGURE 4 Number of PCIs procedures performed per year in each group. PCI, percutaneous coronary intervention. [Color figure can be viewed at wileyonlinelibrary.com]

(>50%) rated 22 factors out of the 26 factors as important, while four factors were rated as less important, including (1) the predicted rate of nonprocedural MI during follow up, (2) previous myocardial infarction (MI), (3) a requirement for femoral arterial access and (4) sex of patient (as shown in Figure 6A). Participants were then divided into six groups based on their level of experience, in order to find out whether the experience level influenced participants' rating or not. Each of the six groups rated the 26 factors similarly (k = 0.72, Cohen's Kappa) (Figure 6B). Table 1 (Supporting Information Materials) compares the rating between all participants in different experience groups. Figure 2 is a central illustration which summarizes our main findings.

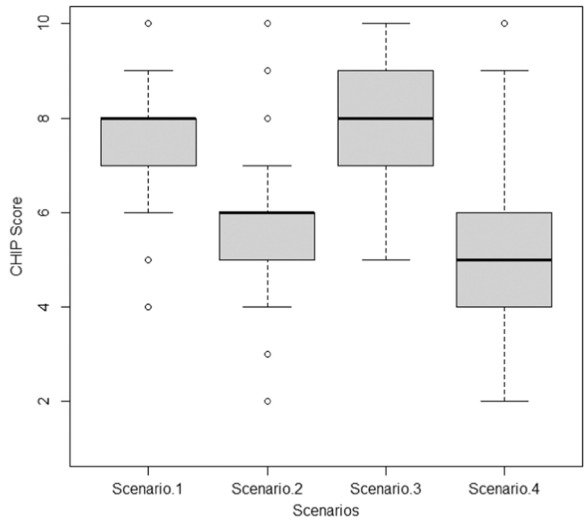

FIGURE 5 CHIP scores in each scenario. CHIP, complex and high-risk percutaneous coronary intervention.

4 | DISCUSSION

Understanding what is meant by complexity and risk for PCI is an important exercise for many reasons, including the implementation of guideline recommended treatments but at present the interventional community appears to have no agreed stance on what constitutes complex PCI. In this current study, we approached the EAPCI, in order to facilitate dissemination of an online questionnaire with the objective of determining attitudes toward complex PCI.[5,11] This study was carried out with the principal aim of determining the agreement between cardiologists, in terms of classifying procedural complexity level and patient risk. This study found that there was poor agreement (k = 0.1) between cardiologists in terms of classification of complexity with only fair agreement (k = 0.31) when determining patient risk. This was surprising, when one considers that the respondents represented a highly experienced group of interventional cardiologists predominantly drawn from across Europe.

As a result of an ageing population, the volume of complex procedures has steadily increased.[12,13] This is reflected in current international guidelines[14] looking at the management of both acute and chronic coronary syndromes, in which antiplatelet regime and duration post-PCI is based on the balance between both complexity and bleeding risk. Whilst there are consensus statements around what constitutes high bleeding risk through the creation of the Academic Research Consortium (ARC) High Bleeding Risk definition,[13] the definitions of what is considered to be complex are much more disparate, with previous definitions being based on anatomical distribution of disease, PCI characteristics, as well as clinical and procedural characteristics. This study set out to establish the baseline agreement across the cardiology community demonstrating that agreement is generally poor and only fair in certain scenarios. On the basis of this lack of agreement surrounding what constitutes complex PCI, it is hard to envisage that guideline recommendations surrounding patient care based on PCI complexity would be consistent and uniform amongst different interventional cardiologists, given that agreement is poor around what is defined as complex PCI.

Agreement among clinicians can occasionally prove challenging as evidenced by several examples such as the numerous tools for cardiovascular risk prediction and the multiplicity of classification tools to define minor, major and life-threatening bleeding post-PCI or related to anticoagulation.[15,16] Similarly, assessing the comparative efficacy of different treatments on clinical outcomes in the setting of complex PCI Is challenging particularly when very heterogenous definitions of what is meant by complex PCI is used across the literature in landmark studies.

Substantial agreement was found between the participants in terms of rating 26 factors that could be used for classifying complex PCI procedures. Interestingly, the level of experience did not show any significant correlation either with risk level or complexity level. Moreover, there was no significant correlation between country based and rating the factors, complexity level and risk level. This study highlights the need for international consensus around what is meant by complex PCI, to allow for more uniform identification of such cases allowing more uniform implementation of guideline recommended therapies, as well as the ability to assess the efficacy of treatments across more uniform populations.

5 | LIMITATIONS

The online survey included a small number of patient cases ($n = 4$) to be rated by the participants; hence, future studies should include a wider range of cases in order to assess agreement regarding complexity. Furthermore, the design of the online survey allowed the participants to skip some questions and, as a result, generated a lot of missing values, hence, a future study should avoid this issue. The provision of still images of coronary anatomy may pose challenges and assessment may have been more effective if the questionnaire had provided video files of the coronary angiogram in different positions. Finally, an important limitation of this study was the low response rate from the survey, which was perhaps to some extent due to the electronic format of the survey, as opposed to face-to-face questionnaires, which themselves come with a certain number of drawbacks, such as lack of anonymity and time constraints. The electronic survey was selected due to increased accessibility to the international community of EAPCI members, as well as the added advantages of relative anonymity and the fact that members had more time to complete the survey in their own time. From the information collected, it would seem that the majority of responders were experienced operators with years of interventional experience, as opposed to trainees and more junior operators.

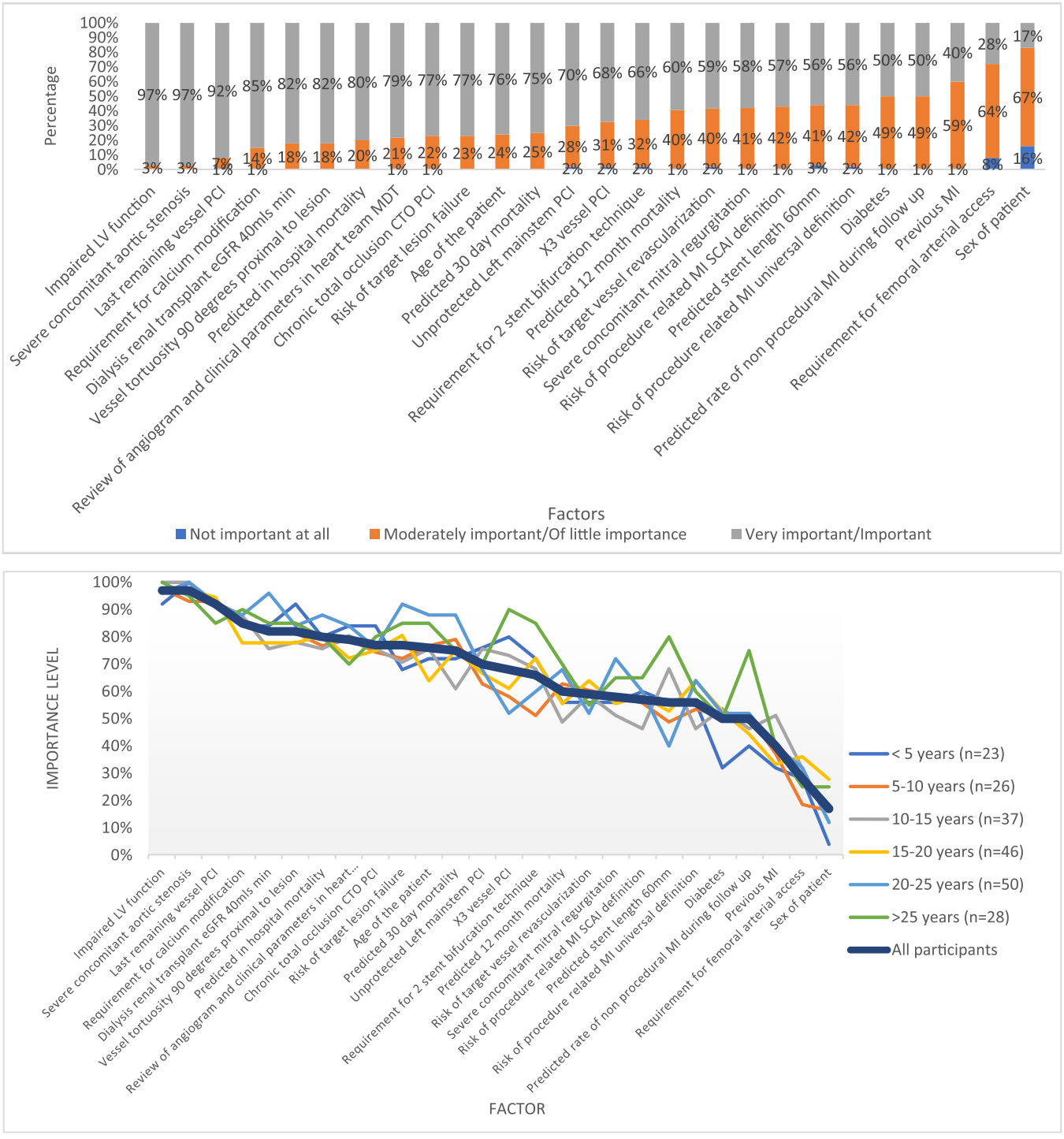

FIGURE 6 Rating the factors for classifying CHIP-PCI procedures. a represents rating the factors between all the participants. b represents importance level of the 26 factors according to the crowdsourcing. Each color in the legend in figure b represents the importance level of those factors based on the level of experience in each group. CHIP, complex and high-risk percutaneous coronary intervention. [Color figure can be viewed at wileyonlinelibrary.com]

6 | CONCLUSION

This study shows that rating complexity and risk level of a PCI case can be challenging, even among cardiologists from the same country and with similar experience levels. In rating the level of complexity, agreement was especially poor, and this could have significant implications in terms of clinical decision-making, patient consent and patient safety. Therefore, agreement between cardiologists should be improved and standardised, perhaps by using a formal checklist/scoring system in order to document both complexity and risk of PCI

cases. This will allow for more uniform implementation of guideline recommended therapies for complex PCI.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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