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Three-dimensional simulation for interventional cardiology procedures: Face and content validity

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Abstract
Introduction and objectives: Three-dimensional (3D) model simulation provides the opportunity to manipulate real devices and learn intervention skills in a realistic, controlled, and safe environment. To ensure that simulators provide a realistic surrogate to real procedures they must undergo scientific validation. We aimed to evaluate the 3D-printed simulator SimulHeart® for face and content validity to demonstrate its value as a training tool in interventional cardiology (IC).
Methods: Health professionals were recruited from sixteen Portuguese IC units. All participants received a 30-minute theoretical introduction, 10-minute demonstration of each task and then performed the intervention on a 3D-printed simulator (SimulHeart®). Finally, a post-training questionnaire focusing on the appearance of the simulation, simulation content, and satisfaction/self-efficacy was administered.
Results: We included 56 participants: 16 ''experts'' (general and interventional cardiologists), 26 ''novices'' (cardiology residents), and 14 nurses and allied professionals. On a five-point Likert scale, the overall mean score of face validity was 4.38±0.35 and the overall mean score of content validity was 4.69±0.32. There was no statistically significant difference in the scores provided by ''experts'' and ''novices''. Participants reported a high level of satisfaction/self-efficacy with 60.7% considering it strongly improved their skills. The majority (82.1%) ''agreed'' or ''strongly agreed'' that after the simulation they felt confident to perform the procedure on a patient.

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Conclusion: The 3D-printed simulator (SimulHeart®) showed excellent face and content validity. 3D simulation may play an important role in future IC training programs. Further research is required to correlate simulator performance with clinical performance in real patients.

Simulação 3D para procedimentos de cardiologia de intervenção – validação da aparência e contéudo

Resumo

Introdução e objetivos: A simulação de modelos tridimensionais (3D) proporciona a oportunidade de manipular dispositivos reais e aprender competências de intervenção num ambiente realista, controlado e seguro. Para garantir que os simuladores fornecem uma comparação realista, estes devem ser submetidos a validação científica. O nosso objetivo foi avaliar o simulador 3D SimulHeart® quanto à validade de aparência e conteúdo, para demonstrar o seu valor como ferramenta formativa em cardiologia de intervenção (CI).

Métodos: Recrutamos profissionais de saúde de 16 unidades de CI portuguesas. Todos os participantes receberam uma introdução teórica de 30 minutos, 10 minutos de demonstração e de seguida tentaram realizar a intervenção num simulador 3D Simulheart. Por fim, foi aplicado um questionário pós-formação com foco na aparência da simulação, conteúdo da simulação e satisfação/autoeficácia.

Resultados: Incluímos 56 participantes: 16 «especialistas» (cardiologistas gerais e de intervenção), 26 «novatos» (internos de cardiologia) e 14 enfermeiros e profissionais aliados. A pontuação média geral da validade de aparência foi de 4,38±0,35, e a pontuação média geral da validade de conteúdo foi de 4,69 ± 0,32, numa escala Likert de cinco pontos. Não houve diferenças estatisticamente significativas nas pontuações de «especialistas» e «novatos». Os participantes relataram um alto nível de satisfação/autoeficácia sendo que 60,7% consideraram que melhoraram fortemente as suas competências. A maioria (82,1%) «concordou» ou «concordou totalmente>» que após a simulação se sentiram confiantes para realizar o procedimento num paciente.

Conclusão: O simulador 3D (SimulHeart®) apresentou excelente validade de aparência e de conteúdo. A simulação 3D pode desempenhar um papel importante nos programas formativos em cardiologia de intervenção. Mais estudos são necessários para correlacionar o desempenho no simulador com o desempenho clínico em pacientes reais.

Introduction

Simulation has been used for training in professions that require precise cognitive and physical tasks in high-risk environments, with potentially fatal complications. Currently, many non-medical professions require simulation as part of routine training or maintenance of competency and annual skills assessment.[1] Multiple high-fidelity medical simulators have been developed, over the past decade, to address the 21st century challenges of rapid expanding new technologies, restrictions in working hours and a demand by regulatory bodies for simulation to be implemented in the medical field.[2]

Interventional cardiology (IC) is a fertile field in which simulation can blossom, because of its highly complex procedures with a long learning curve and that involve life-threatening complications that are prone to a variety of medical errors.[3] By using simulation in IC, the traditional approach ''see one, do one, teach one'' can be replaced with ''learn the operation before the operation room''.[4] However, an international survey of 172 cardiologists showed that only 48% had already participated in simulation training, even though 91% considered it to be ''necessary'' in cardiology.[5] The prevalence of medical errors has been evident since the publication of the Institute of Medicine's report ''To Err Is Human''.[3] Patient safety and prevention of medical errors define one of the rationales for simulation training.

Three-dimensional model simulation is a growing novel tool that can be used for educational purposes, training or individualized medicine, and even patient empowerment. Its versatility enables several shortcomings of clinical simulation to be solved, enabling the standardization of a simulation platform with educational cases that are cheaper

and more practical than traditional or cadaveric training.[6] Simulators based on 3D printing offer an alternative way of learning in an immersive reality with real materials where trainees can make mistakes, repeat, and learn percutaneous intervention skills in a controlled, safe, and realistic environment.

Many studies have shown improvement in operator skills using simulations over traditional mentor-based training in specific IC skill sets.[7–10] Simulator-based training in coronary angiography improved operator skills compared with traditional mentor-based training – including, a shorter procedure time, lower radiation dose used, and a higher global procedure skill score.[7]

The Education and Training European Association of Percutaneous Cardiovascular Interventions (EAPCI) published a recommendation for simulation sessions to be incorporated in training centers of IC[11] and the Accreditation Council for Graduate Medical education requires cardiovascular fellowship training programs to include some component of simulation as part of fellow training.[2] Therefore, in the future, it is expected that simulations will be incorporated into training programs and certification examinations for an interventional cardiologist.

To ensure that simulators provide a realistic comparison to real-life environment they must undergo scientific validation, according to different levels of evidence, following the Kirkpatrick model for evaluating the effectiveness of training.[12]

Objectives

This study aims to evaluate a novel 3D-printed simulator (SimulHeart®) for face and content validity in IC simulation.

Methods

Participants

This study recruited participants from four interventional cardiology simulation courses that occurred between November 2021 and November 2022. All individuals worked in cardiology, including nurses and technicians, medical residents, IC fellows and interventional cardiologists. Interventional cardiology fellows and specialists were defined as ''Experts''; ''Novices'' included cardiology residents and ''nurses and allied professionals'' (NAP) included nurses and cardiology and radiology technicians. All of them performed a simulation protocol on the 3D-printed SimulHeart® simulator. Study design was reviewed and approved by the local research ethics board. Participants were asked to provide written informed consent before enrollment.

Simulation protocol

The simulation protocol started with a 30-minute theoretical introduction. ''Novices'' were briefed on diagnostic coronary angiography and simple coronary intervention procedures, and ''experts'' were exposed to percutaneous coronary interventions (PCI) in complex bifurcations,

Table 1 Tasks performed in the 3D-printed SimulHeart® simulator.

Tasks performed
Selective catheterization of left and right coronary artery by radial or femoral access;
PCI of calcified lesions with rotational atherectomy and/or lithoplasty;
PCI of bifurcation lesions and left main with provisional or two-stent techniques;
PCI in a post-TAVI context and intravascular imaging interpretation (with ultrasound or optical coherence tomography)

calcified lesions, left main, post-transcatheter aortic valve implantation (TAVI) and intravascular imaging.

The simulation required the participants to perform the following tasks: selective catheterization of left and right coronary artery by radial or femoral access; PCI of calcified lesions with rotational atherectomy and/or lithoplasty; PCI of bifurcation lesions and left main with provisional or two-stent techniques; PCI in a post-TAVI context and to perform and interpret intravascular imaging (with ultrasound or optical coherence tomography). All participants received a demonstration of each task (Table 1) and then attempt to perform it for two hours.

After each attempt, participants were given oral feedback by the trainer. In the end, a 30-minute debriefing session was performed.
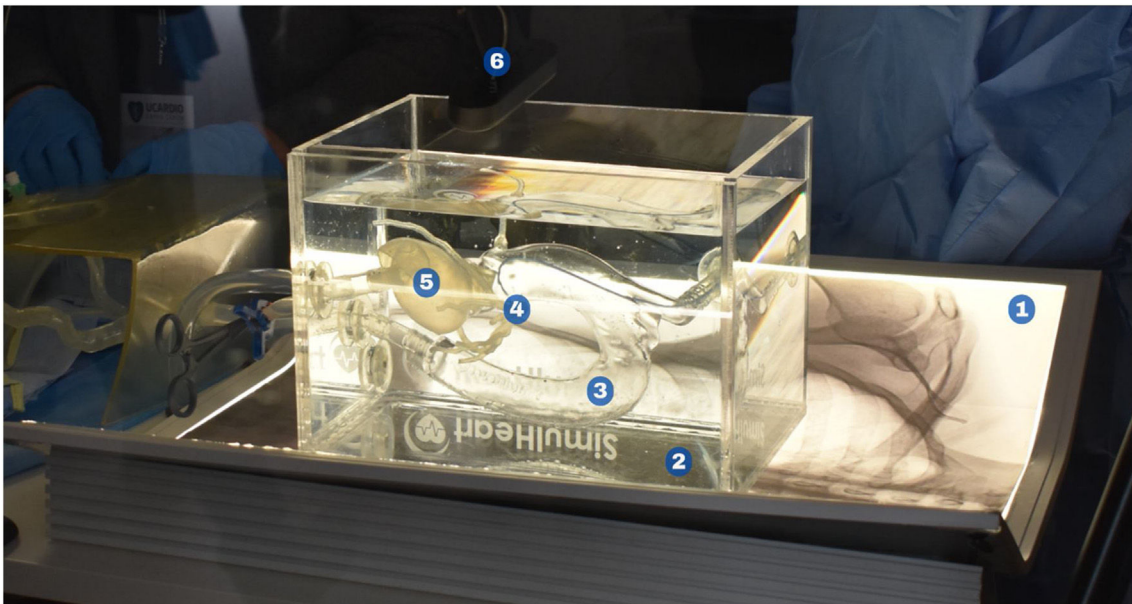
Simulator

The 3D-printing process is a complex three-step procedure (image acquisition, segmentation, and printing), its detailed explanation is out of the scope of this article. The simulator printing process has been previously detailed.[13–15]

Briefly, for the development of the coronary model, computed tomography coronary angiogram data of a real patient was rendered into a 3D volume depicting coronary arteries[16] and digitally manipulated to include coronary stenosis and connector parts to connect them to the simulator. The coronary anatomy was then printed in 3D using a stereolithography printer to obtain the final patient-specific coronary artery model made of custom hybrid flexible material of polyethylene and siliconized rubber, with a dual-layered design and filled with fluid. Finally, the coronary 3D-model was connected to our custom-made interventional cardiology simulator, the SimulHeart® (3D CardioSolutions, Coimbra, Portugal). The simulator (as shown in Figures 1 and 2) includes an acrylic water tank, which is filled with water and where the 3D-printed vascular anatomical structures are inserted. The whole vascular structure is connected to a pumping system to simulate the arterial pressure of a patient, generating an authentic environment during the intervention. Its main features besides the 3D-printed vascular anatomy, include radial and femoral access sites that enable the use of actual diagnostic and interventional devices with realistic haptics feedback. The simulation was performed without ionizing radiation. Participants viewed the simulated procedure through a monitor,

1	Arterial Acess	**4**	Coronary arteries	**7**	Aorta
2	Pump	**5**	Monitor	**8**	Acrylic Tank
3	Left ventricle	**6**	Video camera		

Figure 1   The SimulHeart® simulation setup.

1	Simulated fluoroscopic apperance	**3**	Aorta	**5**	Left ventricle
2	Acrylic Tank	**4**	Coronary arteries	**6**	Video camera

Figure 2   The SimulHeart® simulation setup.

and usual projections were obtained by moving a real-time video camera.

Questionnaire

A post-training questionnaire was applied to all participants (Appendix 1).

The questionnaire was developed by the research team, based on a literature review, and with the collaboration of a panel of specialists in IC from different Portuguese centers. The ''expert group'' met on two occasions, the first meeting to brainstorm possible questions on face and content of the model and satisfaction with the course, and a follow-up meeting to decide the final items to be included on the questionnaire. The questionnaire involved three main areas: (a) Appearance of the simulation; (b) Simulation content and (c) Satisfaction and self-efficacy.

The simulator was assessed for face and content validity and learner satisfaction and self-efficacy, in concordance with definitions published in the literature.[12,17] Face validity is an assessment of realism, in which a defined group of subjects are asked to judge the degree of resemblance between the system under study and the real environment.[17] Content validity examines the level to which the system covers the subject matter of the real performance.[17] The evaluation is carried out by reviewing each item to determine whether it is appropriate for the test and by assessing the overall cohesiveness of the items, such as whether the test contains the steps and skills that are used in a procedure. The reliability of an evaluation instrument relates to its ability to provide consistent results with minimal errors of measurement. Internal consistency was the method used for estimating internal reliability of the questionnaire items.[18]

Face and content validity were evaluated using ''experts'' (level V) and ''novices'' (level III) operator assessments of the simulator. This expertise difference was based on criteria established by EAPCI core curriculum for percutaneous cardiovascular interventions,[11] where level V is defined as ''Performance as the first operator without supervision and ability to teach/supervise more junior colleagues'' and level III is ''Performance as the first operator with reactive supervision, i.e., on request and quickly available''. Using five-point Likert scale participants rated 13 aspects of the appearance of the simulator, eight domains of the content, and seven domains of satisfaction and self-efficacy. Higher scores indicated a more favorable assessment. Thresholds were set *a priori* as mean scores of <3.0, 3.0−4.0, and >4.0 for ''unacceptable'', ''moderately acceptable'' and ''good'', respectively.[19,20]

Statistical analysis

All data were collected and stored in a de-identified database. Continuous data were described using mean ± standard deviation or median (interquartile range), according to the normality of the distribution. Categorical data were represented by frequency and proportion. Statistics were calculated using the IBM Statistical Package for Social Sciences, v28.0 (SPSS). An alpha of 0.05 was set for significance of all statistical tests.

Results

Fifty-six participants completed the study: 16 ''experts'', 26 ''novices'' and 14 NAP from sixteen hospitals across Portugal. No participant had prior experience with the SimulHeart® simulator. Sociodemographic characteristics are explained in Table 2.

The questionnaire showed good values of internal consistency, with a global reliability of 0.93, measured by Cronbach's alpha. The items of face, content, and satisfaction showed an internal consistency of 0.85, 0.81, and 0.87, respectively.

The overall mean score of face validity was 4.38 ([SD 0.35]) (with classifications varying from 2 to 5). The individual frequencies of the items that evaluated face validity are described in Figure 3.

The overall mean score of content validity was 4.69 ([SD 0.32]) (only varying between 4 and 5 classifications) – Figure 4.

In both face and content validity, there was no statistically significant difference in the scores of ''experts'' and ''novices''.

Optional written narrative qualitative assessment by participants showed several common themes. Participants found the simulator to be ''realist'', have ''good fidelity'' and be an ''enriching formative experience''. Some participants, however, considered that the course should have ''more hours of individual training''.

In the questionnaire, satisfaction and self-efficacy were also measured (as shown in Figure 5), 80.4% strongly agreed that the course was well executed and interactive, 75.0% strongly considered the course improved their theoretical knowledge, 60.7% also considered it strongly improved their technique. 67.9% strongly agreed that after the simulation training, they felt confident to explain the procedure to a patient. 82.1% agreed or strongly agreed that after the simulation they felt confident to perform the procedure on a patient. Most participants (85.7%) strongly agreed they would recommend the course to colleagues.

The mean score (on a ten-point Likert scale, with 1 being not relevant and 10 very relevant) in general terms for the relevance of using this model in training was 9.41 (SD 0.80, Range [7−10]).

Discussion

This study showed that the SimulHeart® simulator for percutaneous interventions met the criteria for both face and content validity at a ''good'' level, based on the predefined definitions of validity. The simulator presents excellent realism and simulates all the procedure steps. Also, there was a high level of satisfaction and self-efficacy with the training in this model, with increased confidence.

Simulation is breaking barriers in the modern era of medical and surgical education. With ever increasing pressures on surgical performance, the profession is eagerly looking for training systems that are novel, reproducible, and validated. The reality is trainees are operating less than ever before[21] due to shortened training programs, reduced working hours,[22] and advancement of medical and minimally invasive techniques, therefore the application of 3D
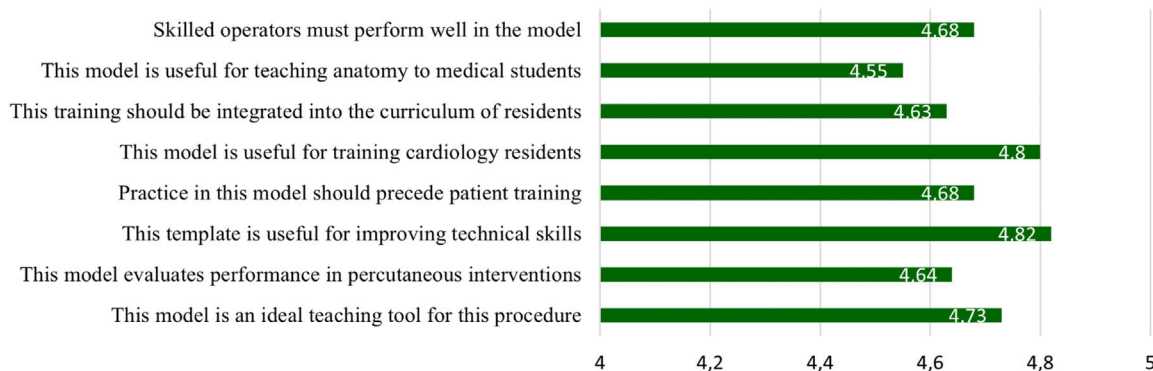
Table 2 Participants sociodemographic characteristics.

	Total	Novice	Experts	Other
(n)	56 (100%)	26 (46.4%)	16 (28.6%)	14 (25%)
Gender	F – 25 (44.6%)	F – 13 (50%)	F – 4 (25%)	F – 8 (57.1%)
	M – 31 (55.4%)	M – 13 (50%)	M – 12 (75%)	M – 6 (42.9%)
Age	Mean: 35.6 ([26–60])	Mean: 29.3 ([26–35])	Mean: 31.1 ([31–60])	Mean: 44.3 ([30–55])

Face validity
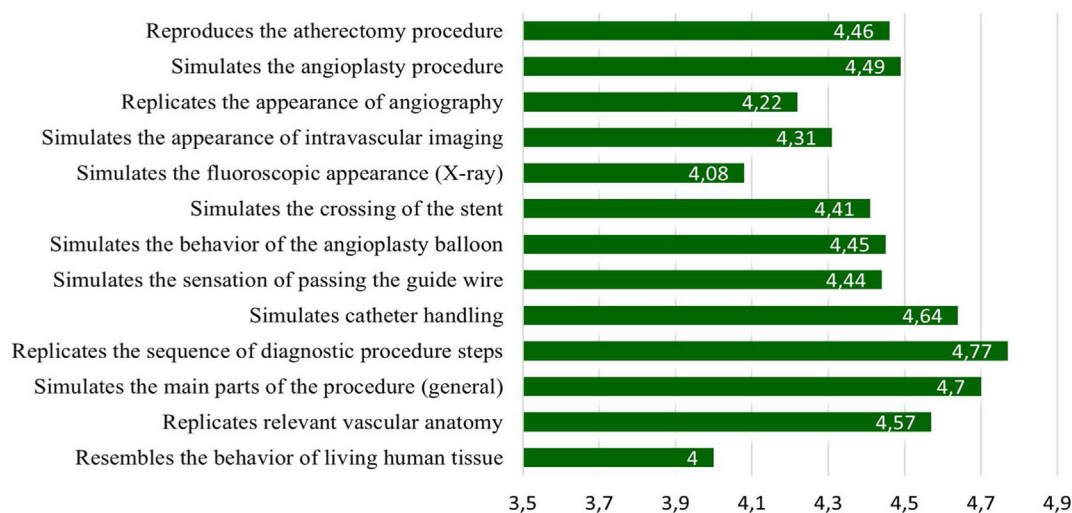
Figure 3 Mean face validity of individual items of the post-simulation training questionnaire.

Content validity

Figure 4 Mean content validity of individual items of the post-simulation training questionnaire.

simulation technology is evident. This is particularly important in training for minimally invasive percutaneous procedures, which are complex and leave little space for error. In this area a valid 3D simulator may reduce the learning curve and improve patient safety. This modality of simulation affords a unique opportunity for trainees to practice reality-based surgical skills without any risk to the patients.

While there are studies on 3D simulators for patient-specific percutaneous interventions,[13,23–30] there is minimal data in the literature on the validation of 3D model

simulators for training in cardiology. Common benchmarks on which simulators are judged include reliability, face, content, construct, and predictive validities.[31] Even though there are some validated training devices and protocols for coronary angiography, this area has few well-established or validated tools.

A 2019 study with Simbionix Angio-Mentor (Simbionix USA, Cleveland, Ohio) documented a significant improvement of skills in real-world practice (coronary angiography in patients) after simulator-based training.[7] According to
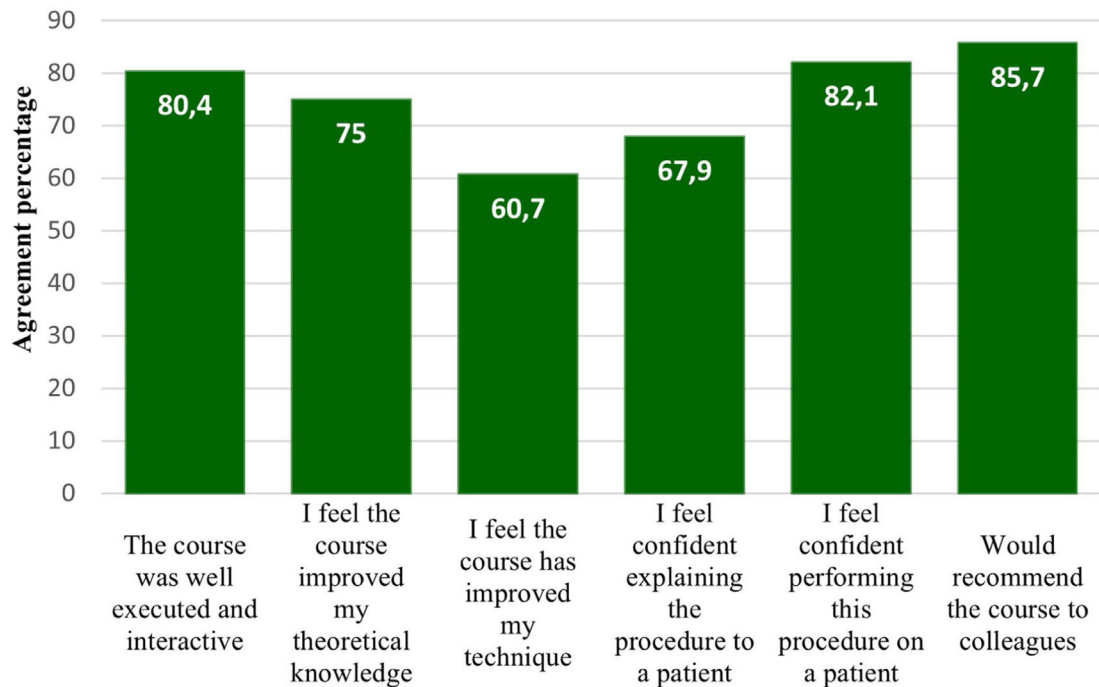
Figure 5 Percentage agreement on satisfaction and self-efficacy of individual items of the post-simulation training questionnaire.

Popovic et al., the simulation group showed significant improvement in respect to contrast use, procedural time, fluoroscopic time, and global performance score in coronary catheterization in patients in the cardiac catheterization lab after four hours of high-fidelity simulation training in comparison to a control group. These findings documented an improved intra-operator performance in the clinical setting before and after simulation training demonstrating the impact of simulation on the transference of skills to real-life practice. They concluded that ''simulation can be used as an assessment tool by defining a mastery threshold ensuring all individuals have reached a predefined level of proficiency to enable safe patient care''.

However, there is room for improvement. The criteria with the lowest scores were ''resembles living human tissue'', with a mean score of 4.00, and ''simulates the fluoroscopic appearance (X-ray)'', with a mean score of 4.08. These items would score higher if the simulation took place in an actual catheterization laboratory, with radiation and sterile drapes. That environment undoubtedly lacks practicality for widespread practical courses.

Despite the possible limitations, most participants (96.40%) ''agreed'' or ''strongly agreed'' that the training in the simulator should be integrated into the cardiology residency curriculum. Furthermore, the improved subjective confidence of ''novices'' participants suggests a benefit from training in the simulator and supports its use as an educational tool.

The categorization of participants as ''experts'' or ''novices'' was based on the definition of the EAPCI curriculum and was self-reported in the questionnaire by the participants. One of the limitations of our study was overall participant numbers were low (n=56), a more significant sample could have more statistical power to detect differences between groups and to evaluate construct validity. Expanding the study to a larger number of participants would be reasonable based on our results.

For future investigation construct validity should be performed on the model. Further research is required to correlate simulator performance to clinical performance in a real patient.

Conclusion

The SimulHeart® simulator built by 3D CardioSolutions showed a good level of face and content validity. There was a high level of satisfaction and efficacy, as well as improved confidence. Both ''experts'' and ''novices'' participants agreed that training in the simulator should be incorporated into the cardiology residency curriculum.

Based on our study, we suggest training in this simulator should be used in interventional cardiology for medical residents, fellows, and allied professionals to gain experience and skill in a safe environment.

Conflicts of interest

The authors have no conflicts of interest to declare.

Acknowledgment

Appendix A. Supplementary data

Supplementary material associated with this article can be found in the online version at doi:10.1016/j.repc.2023.11.006.

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