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The Heart-SIMS-1: Simulation Training for Invasive Cardiovascular Procedures

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THE HEART-SIMS-1: SIMULATION TRAINING FOR INVASIVE CARDIOVASCULAR PROCEDURES

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Abstract

Introduction: The use of three-dimensional simulation training (ST) for invasive cardiovascular procedures is an effective tool providing a controlled and safe environment for students to practice complex procedures without risking real patients during the learning process. We aim to assess the impact of ST compared to classical teaching of coronary angiography among medical students and to raise awareness for the importance of simulated training in interventional cardiology.

Methods: 28 medical students in their sixth year will attend a theoretical learning session on coronary angiography. They will be randomized in 2 groups: a conventional training (CT) group (n=14) and a ST group (n=14). CT group will visualize a 20-minute video-recorded simulation procedure, while ST group will perform coronary angiography simulated training with SimulHeart® in groups of two, also for 20 minutes. After the training session, students' knowledge will be assessed through a theoretical multiple-choice exam and a practical evaluation in a catheterization laboratory using SimulHeart®.

Results: We expect superior performance both in theoretical and practical tests in the ST group compared to CT group. We also anticipate that this project will encourage a broader adoption of ST as a tool for teaching medical students in the field of interventional cardiology.

Discussion and conclusion: ST might play an important role in medical education. In the field of interventional cardiology, it can lead to better understanding of coronary anatomy and practical skills. Proficiencies acquired through ST might be applicable to real-word clinical situations. Additional research is needed to establish a correlation between simulation training and future clinical performance in real patients.

Keywords: Education, Invasive coronary angiography, Cardiovascular procedures, 3D-printing, Simulation training

1. Introduction

The origins of the simulation-based training (SBT) retrace to the aviation industry. The first flight simulators were used to help pilots develop their skills in a controlled and safe environment, replicating the experience of flying and providing a way to practice maneuvers, learn to handle emergencies, and improve overall skills without the risks associated with real flight. The success of simulation training (ST) in the aviation industry has inspired its application in various other fields, including healthcare and other high-risk industries, where the simulation of real-world scenarios is essential for training individuals to handle complex situations effectively and safely(1).

Simulation has been used for educational purposes in practical activities that need high precision, extensive training to achieving proficiency, and where even a minimal technical error can bring serious consequences. Considering this, ST has been utilized for trainees in surgical and interventional fields such as anesthesia, urology, vascular surgery and interventional cardiology (IC), demonstrating an improvement in the abilities of novices(2–4). IC presents an opportune arena in which SBT can thrive. The learning curves in IC and the relationship between volume and outcomes suggest that simulation has the potential to enhance clinical results. With the emergence of three-dimensional (3D) printing, there is the possibility of an innovative technology that can replicate vascular anatomy and allows simulation experiences(5). The use of ST for invasive cardiovascular procedures is considered an effective tool providing a controlled and safe environment for practicing complex procedures without risking real patients, thus minimizing potential harm and human errors during the learning process. The repetitive practice increases performance and skills of trainees which enhances their confidence and competence. This can lead to reduced anxiety and more effective performance in the actual clinical setting. Simulation can offer a variety of clinical scenarios that may not be readily accessible in real clinical practice. This helps students prepare for a broader range of clinical situations than those encountered in a conventional learning environment(6).

Poor knowledge retention is one reason for struggles faced by medical student in learning and has been a huge concern in medical education. Classical medical teaching usually comprises formal theoretical sessions (grand lectures) and practical training in smaller groups with patients. When it comes to simple invasive procedures, the rule “see one, do one, teach one” still holds these days. With advances in technology, 3D simulation-based teaching has evolved as a learning tool in medical education to improve student learning outcomes. Developing a new tool for medical education using 3D printing highlights the importance of defining educational objectives and addressing the learning gap. The goal is to teach anatomy, facilitate pre-procedural planning, and foster the development of technical skills of beginners, through the visualization of the structural connections between anatomical components with 3D models(7). Several studies showed the effectiveness of 3D models in short and long-term knowledge retention in human anatomy courses as compared to traditional teaching methods among medical students(8,9). Patient-specific models with anatomical fidelity have the potential to significantly improve the knowledge and skills of a new generation of medical students(7).

Several studies have shown that SBT in invasive coronary angiography (ICA) yields enhanced skill development and reduced error rates when compared to conventional mentor-based training methods(9–15). Fischer and co-authors randomized 118 medical students to virtual simulation-based ICA training and traditional power-point lectures, showing an increase in performance scores assessed by a multiple-choice test with 40 questions (0-100 points) in the simulator group (59.5 vs 43.7, P<0.01). Student satisfaction was also higher in the simulator group (58 vs 44)(9). Furthermore, SBT has been found to provide superior performance scores, assessed by measures such as fluoroscopy duration and total procedure time, providing evidence of effective knowledge transfer to real-life scenarios within the catheterization lab(15). This observation was corroborated by Prenner and co-authors, showing shorter procedure time (23.98 min vs 24.94 min, P=0.03) and significant less radiation exposure (56,348 mGycm2 vs 66,120 mGycm2, P<0.001) in fellows pre-exposed to virtual simulators (n=12) compared to the remaining fellows (n=20)(11). Wolfram Voelker *et al.* randomized 18 cardiology fellows to virtual reality ST (n=9) or controls (n=9), reporting a higher “skill score” comprising 14 performance characteristics (5-level Likert scale, maximum score of 70 points) in the former group, assessed in a 3D-printed model, after a simple (pre-evaluation) and more complex (post-evaluation) catheter intervention on a pulsatile coronary flow model in a catheterization laboratory(12). Popovic and co-authors randomized 20 cardiology residents to SBT group (n=10) and control group (n=10) to access “performance score” including procedure time, fluoroscopic time, and contrast amount. The procedure time was shorter (P=0.002), the radiation dose lower (P=0.001), and the global procedure skill was higher (P=0.0001) in the ST group compared to control group(13). All those studies suggests that ST in ICA is a promising novel learning tool and should be incorporated into future medical curriculum. Table 1 summarizes the studies on ST for performing ICA.

Even though SBT is a promising educational tool for ICA, its effectiveness depends on how it is integrated into the educational curriculum and practical clinical training. The team in charge for this study has experience with custom-made 3D-printed simulators fully compatible with standard catheterization laboratory tools, which are able to replicate diagnostic and interventional coronary procedures, such as the SimulHeart®(5). 3D printed simulators offer several advantages: they are inexpensive to produce and maintain, the modular design enables a multitude of training sessions with virtually any anatomy, they can be used without ionizing radiation and the haptic sensations are very similar to real-life procedures. Combining conventional educational approaches with simulation can provide a more comprehensive training experience(16). This study aims to provide evidence that the SBT for medical students is more effective than conventional educational models for acquisition of anatomical and procedural knowledge in the field of cardiology.

Our global aim is to assess whether mentored SBT with 3D printed models can improve the anatomical knowledge, procedural skills, and safety performance of beginners in coronary diagnostic procedures. The specific primary objective is to assess the impact of simulated training compared to classical teaching of ICA among medical students. The specific secondary objective is to raise awareness for the importance of simulated training in IC training.

Table 1: Summary of studies on SBT for ICA

Citation	Population	Type of simulation	Intervention (n)	Control (n)	Evaluation methods	Results
Akshay Bagai MD, *et al.*(10)	27 cardiology trainees	Virtual reality simulator (MENTICE VIST)	12	15	Technical and global cardiac catheterization performance assessed baseline and reassessed 1 week after ST	Improvement in technical performance was greater in the simulator group compared with the control group (6 versus 1; P=0.04)
Prenner SB., *et al.*(11)	32 cardiology fellows	SBT (VIST@-C)	12	20	Assessment of procedures performed by 12 cardiology fellows who underwent simulation-based training and procedures performed by 20 traditionally trained fellows	Procedures performed by fellows trained with SBT were shorter (23.98 min vs 24.94 min, P=0.034) and were performed with decreased radiation (56,348 $mGycm^2$ vs 66,120 $mGycm^2$, P<0.001). Training on the simulator was independently associated with 117 fewer seconds of fluoroscopy time per procedure (P=0.04).
Voelker W., *et al.*(12)	18 cardiology fellows	Virtual reality simulator (CoroSim®)	9	9	"Skills score" comprising 14 performance characteristics after a simple (pre-evaluation) and more complex (post-evaluation) catheter intervention on a pulsatile coronary flow model in a catheterization laboratory	Higher "skills score" in the simulation group: increased by 5.8 in the Virtual Reality simulation group and decreased by 6.7 in the control group (P =0.003) from the simple stenosis at pre-evaluation to the more complex lesion at post-evaluation
Fischer Q., *et al.*(9)	118 medical students	Virtual reality simulator (Mentice VIST-lab)	59	59	Score in 40 multiple choice questions (0-100 Points) and a simple questionnaire about student's satisfaction (yes or no)	There was an increase in performance scores in the simulator group (59.5 vs 43.7, P<0.01). Student satisfaction was also higher in the simulator group (58 vs 44)
Casey B., *et al.*(17)	7 First-year cardiology fellows	SBT (AngioMentor™ simulators)	7	No control group	Total time, contrast and total fluoroscopic time used to complete the benchmark case requiring basic coronary procedures one day later and at 9 months following 2-3 months of training in the cardiac catheterization lab	All fellows improved total time to complete the benchmark case from initial to second attempt one day later (14:56 on Day 1, 8:30 on Day 2, P=0.03). Total contrast used (60mL on Day 1, 39mL on Day 2, P=0.11) and total fluoroscopic time (6:30 on Day 1 and 4:26 on Day 2, P=0.16) also both decreased.

Citation	Population	Type of simulation	Intervention (n)	Control (n)	Evaluation methods	Results
Popovic B., *et al.*(13)	20 cardiology residents	SBT (Simbionix AngioMentor)	10	10	Performance score: including procedure time, fluoroscopic time, contrast amount among others	The procedure time was shorter (P=0.002), the radiation dose lower (P=0.001), and the global procedure skill was higher (P=0.0001) in the ST group compared with the control group
Wibowo G., *et al.*(14)	34 cardiology trainees	3D-printing-based fluoroscopic simulator	17	17	Both groups were evaluated with a pretest, post-test I and post-test II, consisting of 17 multiple choice questions and three essay questions	The delta between the post-test I and the pretest of the simulation group was higher than the delta between the post-test I and the pretest of the group using conventional learning media (8.53 vs 5.21, P=0.003)
Jensen UJ., *et al.*(15)	16 senior cardiology residents	Virtual reality simulator (Mentice VIST system)	8	8	Skills metrics and errors were compared between the groups in two consecutive coronary angiographies on patients	The virtual reality-trained group had shorter fluoroscopy time (558 vs 842 sec, P=0.003) and total procedure time (1,356 vs 1,623 sec, P=0.006) than the controls. The controls had higher error score (27 vs 15, P=0.002) and lower performance score (47 vs 68, P=0.006) than the virtual reality-trained group

2. Methods

This manuscript is a study protocol of *The Heart-SIMS-1: Simulation Training for Invasive Cardiovascular Procedures*.

Participants:

Twenty-eight sixth-year medical students will be invited to participate in an ICA training session at *Centro de Simulação Biomédica dos Hospitais da Universidade de Coimbra* (Coimbra, Portugal), and none of them had experience in IC. All participants will have signed the informed consent, voluntarily accepting to take part in the study.

This study is an investigators' initiative trial of SBT for medical students in coronary diagnostic procedures - Heart-SIMS-1. As a pilot study, the sample size is small, but it will serve as a basis for planning a larger clinical trial, thereby acting as a starting point to understand which metrics are appropriate to be used.

Study protocol:

The simulation protocol starts with a theoretical learning session on ICA (60 minutes), encompassing the learning objectives (coronary anatomy, procedural indications, and safety considerations) for all participants. During the theoretical session, students will be instructed on the most utilized tools for conducting coronary catheterization, along with a step-by-step sequence of the procedure. Medical students will be then randomized to two training methodologies using Python programming language (1:1), at the same location: a conventional training (CT) group (n=14) and a simulation training (ST) group (n=14). No pre-testing will be performed, because medical students, unlike residents, have limited knowledge on ICA, and randomization will naturally balance both groups. The CT group will visualize a video-recorded simulation procedure with duration of 20 minutes, in which the steps of the ICA are explained in the same 3D-printed simulator as ST group. The ST group will perform ICA simulated training with 3D printed simulator SimulHeart® in groups of two, with debriefing and feedback. Participants will be taught on how to perform each step of the procedure and guide on safety measures concerning catheter handling, radiation exposure, and contrast administration. The duration of ICA simulated training will be 20 minutes per group. Both types of sessions will have the same instructions and duration (20 minutes). There will be time for questions and answers.

Evaluation:

After the training session, students' knowledge will be assessed through a theoretical multiple-choice exam, assessing basic coronary artery anatomy knowledge, procedural indications, and safety considerations (scored 0-100 points) (Appendix III) and a practical evaluation (Fig.1).

The practical evaluation will take place in a catheterization laboratory using SimulHeart® simulator at *Unidade de Intervenção Cardiovascular (UNIC), Serviço de Cardiologia do Centro Hospitalar e Universitário de Coimbra* (Coimbra, Portugal). The simulator will be under surgical drapes to mimic a real procedure in a real catheterization laboratory.

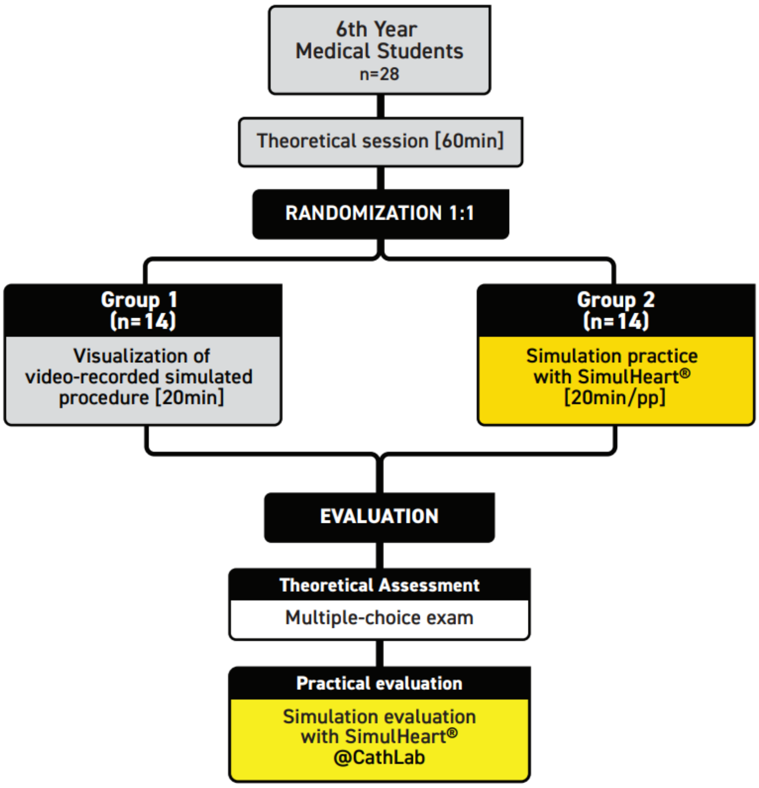

Figure 1: Heart-SIMS-1 workflow

The participants will have to perform pre-specified steps during practical session of diagnostic ICA. The procedure will be video-taped and rated based on performance time, execution of pre-specified steps and monitoring of safety requirements. The student's performance will be evaluated (scored 0-100 points) in real-time and subsequently through review and the analysis of the recorded videos by experts interventionalists, blinded to the randomization and under a checklist of pre-specified safety endpoints and a performance evaluation checklist. The safety endpoints serve as a marker of the overall performance and are not specific to ICA. These endpoints encompass the contrast dosage, procedural duration, and the absence of red flag maneuvers (catheter appropriate purge before contrast injection; pressure evaluation before contrast injection; advancement of catheter over-the-wire; and decannulation of the catheter before guidewire advancement in coronary ostium). The performance evaluation checklist is an ICA procedure-specific evaluation, including an assessment of separate tasks that are fundamental in performing ICA. All the evaluated parameters during the practical session of simulated diagnostic ICA were summarized using a score, adapted from Popocic B. *et al.* (Table 2) and Chaer R.A. *et al.* (Table 3)(2,13).

Following this, the collected data will be analyzed and statistically processed.

Table 2: Safety Endpoints, adapted from Popovic *et al.*(13)

Safety endpoints	Score
Contrast dosage (<100 ml)	15
Procedural duration (<15 minutes)	15
Absence of red flag maneuvers	18
Total	/48

Table 3: Performance evaluation checklist for ICA, adapted from Chaer *et al.* (2)

1.	Diagnostic catheter appropriate purge	☐0 ☐2 ☐4
2.	Introduction of the 6F catheter on guidewire in the radial sheath	☐0 ☐2 ☐4
3.	Advancement of the LCA diagnostic catheter into the aortic root	☐0 ☐2 ☐4
4.	Withdrawal of the guidewire	☐0 ☐2 ☐4
5.	Fluoroscopy-guided catheter engagement of the left coronary ostium	☐0 ☐2 ☐4
6.	Contrast injection in the LCA	☐0 ☐2 ☐4
7.	Over-the-wire withdrawal of left coronary artery diagnostic catheter	☐0 ☐2 ☐4
8.	Advancement of the RCA diagnostic catheter into the aortic root	☐0 ☐2 ☐4
9.	Withdrawal of the guidewire	☐0 ☐2 ☐4
10.	Fluoroscopy-guided catheter engagement of the right coronary ostium	☐0 ☐2 ☐4
11.	Contrast injection in the RCA	☐0 ☐2 ☐4
12.	Over-the-wire diagnostic catheter withdrawal	☐0 ☐2 ☐4
13.	Final hemodynamic check	☐0 ☐2 ☐4

Maximum score=52. LCA, left coronary artery; RCA, right coronary artery.

Scoring guide:

0=fail; **2**=success, not very good; **4**=success, good

<u>Simulator:</u>

The ST group will perform ICA simulated training with 3D printed simulator SimulHeart® from 3D CardioSolutions (Coimbra, Portugal). The SimulHeart® is a realistic interventional cardiology simulator designed for utilization in regular catheterization laboratories. Its main features comprise 3D-printed vascular anatomy, along with both radial and femoral access points that facilitate the use of authentic diagnostic and interventional tools, providing a realistic haptic feedback experience (Fig.2).

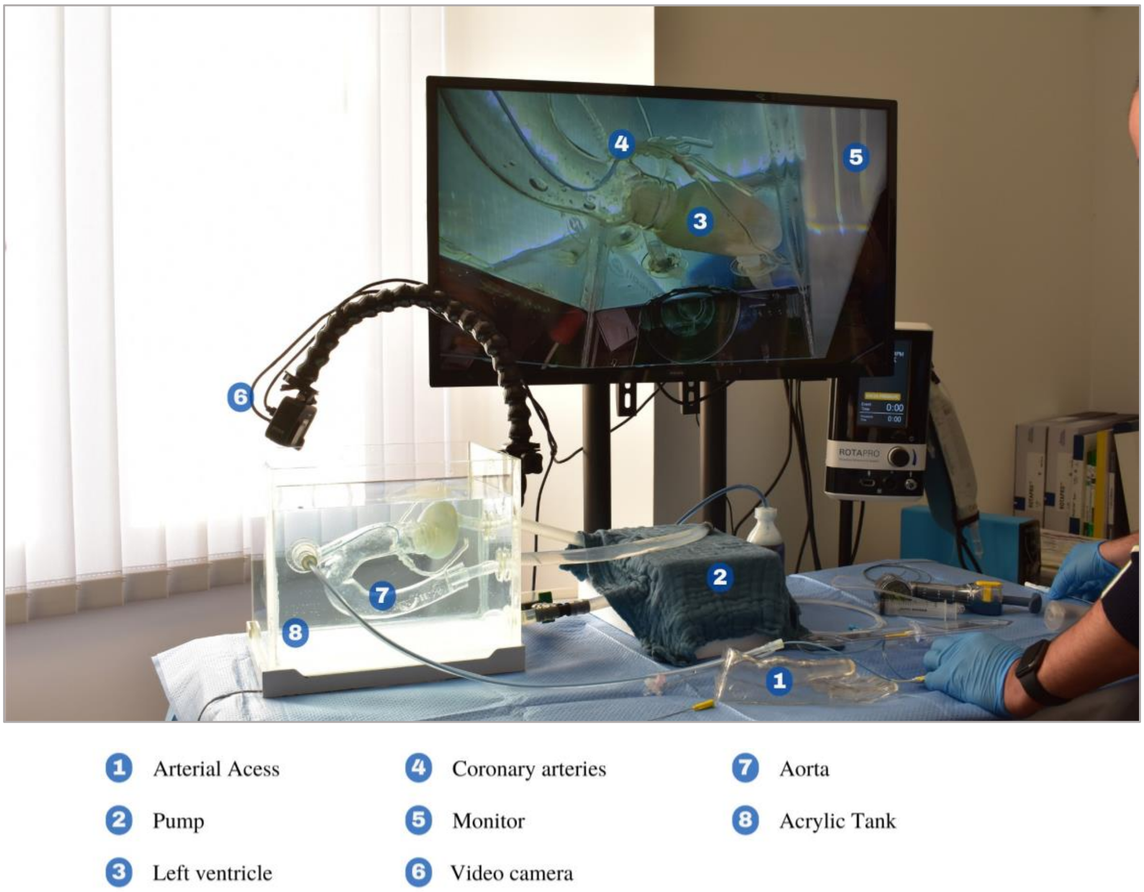

Figure 2: The SimulHeart® setup. Adapted with permission from Sequeira C., *et al.*(18)

The 3D printing process is complex and includes three steps: image acquisition, segmentation, and printing. The explanation of the printing process is out of scope of this article and already explained in literature(5,19–22). Once printed, the coronary artery 3D model is connected to the custom-made interventional cardiology simulator, SimulHeart®.

Statistical analysis:

The primary endpoint will be final performance score (0-200). Continuous data will be described using mean ± standard deviation or median (interquartile range), according to the normality of the distribution. Statistical analyses will be conducted using the IBM Statistical Package for the Social Sciences, v28.0 (SPSS). T student or Mann-Whitney tests will be used for groups comparison. A significance level of 0.05 will be used to test for statistical differences. This is a pilot study, without sample size calculation.

Timeline:

Table 4 represents the time that will be allocated to each stage of the study.

Table 4: Study timeline

Tasks	Duration	Month1	2	3	4	5	6	7	8
Study approval and screening	3 months								
Sessions T1 and T2	1 month								
Performance evaluation	1 month								
Publication	3 months								

Ethical Considerations:

Study design with process number OBS.SF.052-2023 was reviewed and approved by the local research ethics board- *Comissão de ética para a saúde do Centro Hospital e Universitário de Coimbra (CES)* (Appendix I).

Participants will be asked to provide written informed consent before enrolment (Appendix II). The practical part of the evaluation, conducted in the hemodynamics laboratory of CHUC, will involve exposing the students to a very low dose of ionizing radiation, for which all necessary personal protective equipment will be provided. For this reason, pregnant students should not participate in the clinical study.

3. Expected Results

Based on the existing literature about ST for ICA and for medical teaching in general, we hypothesize that ST will enhance the learning process, demonstrated by superior performance both in theoretical and practical tests compared to CT group, despite equal contact hours. This suggests that students undergoing ST will find it easier to acquire theoretical knowledge of coronary anatomy and its spatial representation. Additionally, they will be better prepared to transition to clinical practice, being more familiar with the tools used in the IC laboratory, the procedural steps, and safety considerations.

We also anticipate that this project will encourage a broader adoption of ST within the interventional cardiology community, and specifically, as a tool for teaching medical students.

4. Discussion

This study represents one of the first attempts to evaluate the effectiveness of SBT with 3D-printed simulators for medical students in coronary diagnostic procedures. As a pilot study, the sample size is small, and larger studies are necessary to fully understand the impact of simulation on medical students' education. We anticipate reporting improved scores in both theoretical and practical knowledge for students in the ST group compared to those in the CT group. According to the literature, we believe that the superior scores observed in the ST are linked to the attainment of a more comprehensive understanding of the 3D structure of cardiovascular imaging, potentially enhancing the long-term knowledge retention by transfer(23,24). ST facilitates transference of book-based knowledge into practical skills, improving patient care in daily practice. Popovic *et al.* provides an assessment of the ST impact on real-life performance in the catheterization laboratory, documenting a significant improvement of skills in clinical care after SBT(13). Moreover, simulation can serve as an assessment tool, establishing a standardized minimum proficiency level that should be achieved by all students.

Bagai *et al.* concluded that “less proficient operators derive greater benefit from simulator training than more proficient operators”, suggesting that ST may be more effective in the early stages of medical education. The adoption of SBT for acquiring medical knowledge for performing diagnostic ICA can offer substantial advantages, particularly for beginners.

The ST will be set up under surgical drapes to mimic a catheterization performed on an actual patient and using realistic catheterization tools. It allows a gradual transfer of learning and has become an essential tool in cardiology teaching. While the expression “see one, do one, teach one” reflects an old tradition where patients were used as the primary subject of medical education, the principle “never the first time on the patient” clearly highlights the importance of simulation teaching in medicine. With advancements in ST, this principle could soon be replaced by “never the first time without simulation training”(25).

Although there have been investigations on 3D simulators for patient-specific percutaneous interventions(5,26–32), and for the training of cardiology residents(10–15,17,33), there is minimal data in the existing literature regarding the incorporation of 3D ST into the curriculum for medical students(9). More studies with a robust methodology assessing the interest of SBT in cardiology are needed.

In the present study, students from both groups (ST group and CT group) will be taught for an identical duration and evaluated with the same methodology (both with theoretical multiple-choice exam and practical evaluation in the simulator), limiting evaluation bias. During the practical evaluation in the simulator, students will be assessed based on the fulfillment of safety endpoints (Table 1) and a performance evaluation checklist (Table 2). The performance evaluation checklist serves as a comprehensive summary of all evaluated steps during the practical session of simulated diagnostic ICA. We expect a reduction in contrast volume, preventing nephrotoxicity; a decrease in procedural duration, minimizing radiation exposure; and a higher global performance score in the simulation group compared to the CT group.

Our study differs from most existing data as it focuses on assessing medical students rather than medical doctors. Additionally, it is not a ST study: each student will participate in a single simulation session, with knowledge evaluation conducted immediately afterward, in contrast to training studies where the exposure to simulation varies and is prolonged over time.

No pretesting will be performed before the randomization because medical students didn’t have exposure to interventional cardiology before. The randomization process excludes the selection bias.

Despite the major difficulties to integrate ST in medical education programs, including high costs, limited access to simulation centers and lack of standardized curriculum, its incorporation has the potential to significantly enhance the knowledge and skills of future physicians. Some of these obstacles may be overcome with development of standardized and validated simulation-based curricula. With technological advancements, it becomes imperative to conduct larger-scale studies with rigorous methodology to assess the impact of ST across various medical specialties, particularly in the field of IC.

Some limitations of the study include the limited sample size and the lack of long-term evaluation. Reassessing the students after a certain period could yield valuable data on the long-term retention of knowledge and skills. Another limitation of the study includes the potential bias introduced by training and being evaluated with the same simulator in the ST group. Although efforts were made to mitigate this bias, such as incorporation of a video-recorded simulation procedure in the same 3D-printed simulator for CT group and the placement of the simulator under surgical drapes in a catheterization laboratory for a different impact, it remains a factor that may influence the study outcomes. Additionally, there is the bias associated with muscle memory: participants may retain certain motor skills or reactions from the training sessions, which could impact the evaluation results.

Additional research is needed to establish a correlation between simulation performance and future clinical performance in real patients.

This study aims to assess the impact of simulated training as a valuable tool, enhancing the learning process both in theoretical and practical skills.

5. Conclusion

Based on the existing literature, SBT has become the cornerstone of medical education, enabling high-quality training in a completely safe environment for patients. We expect to demonstrate that SBT in ICA significantly enhances students' performance in both theoretical and practical assessments, even with equal contact hours. Additionally, the findings of this study are expected to promote broader acceptance of ST within the interventional cardiology community.

Our goal is to provide students with the tools to shift from theoretical academic learning to clinical practice. Unlike conventional teaching, proficiencies acquired through virtual reality ST, such as the conversion of a 2-dimensional video image into 3D operational space with tactile response, might be applicable to real-world clinical situations.

6. List of abbreviations

3D- Three-dimensional

SBT- Simulation-based training

IC- Interventional Cardiology

ICA- Invasive coronary angiography

CT- conventional training

ST- simulation training

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8. Conflict of interest

The authors have no conflicts of interest to disclose.

9. Author Contributions

BL and MOS contributed equally to the conceptualization, writing and revision of the work. LG contributed to the writing – review and editing of the work.

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Appendix I- Approvement by the local research ethics board (in Portuguese)

REPÚBLICA PORTUGUESA
SAÚDE

SNS SERVIÇO NACIONAL DE SAÚDE

CHUC CENTRO HOSPITALAR E UNIVERSITÁRIO DE COIMBRA

Comissão de Ética

Exmo. Senhor
Dr. Nuno Deveza
Digmº Diretor Clínico do CHUC

SUA REFERÊNCIA	SUA COMUNICAÇÃO	NOSSA REFERÊNCIA	DATA
		N.º 257/CES	10-07-2023
		Proc.Nº **OBS.SF.052-2023**	

PI OBS.SF.052-2023 *"THE HEART-SIMS-1: TREINO DE SIMULAÇÃO PARA REALIZAÇÃO DE PROCEDIMENTOS CARDIOVASCULARES INVASIVOS"*
Entrada na UID: 23-03-2023
Entrada na CES: 01-06-2023
Investigador/a/es: Manuel de Oliveira Santos – Assistente Hospitalar de Cardiologia do CHUC
Coordenador/a/es: Manuel de Oliveira Santos
Co-Investigador/a/es: Bárbara Gouveia Costa Lobo, João Pedro Borges Rosa, Lino Manuel Martins Gonçalves
Promotor: Não aplicável
Serviço de Realização: Serviço de Cardiologia do Centro Hospitalar e Universitário de Coimbra

Cumpre informar Vossa Ex.ª que a CES - Comissão de Ética para a Saúde do Centro Hospitalar e Universitário de Coimbra, reunida em 21 de Junho de 2023, após reapreciação do projeto de investigação supra identificado, emitiu o seguinte parecer:

"A Comissão considera que se encontram respeitados os requisitos éticos adequados à realização do estudo, e emite parecer favorável ao seu desenvolvimento no CHUC".

Mais informa que a CES do CHUC deverá ser semestralmente atualizada em relação ao desenvolvimento dos estudos favoravelmente analisados e informada da data da conclusão dos mesmos, que deverá ser acompanhada de relatório final.

Com os melhores cumprimentos,

11/7/23
Dr. Nuno Deveza
Diretor Clínico
C.H.U.C. - EPE

A Comissão de Ética do CHUC, E.P.E

Dra. Cláudia Santos
Presidente

CES do CHUC: Dra. Cláudia Santos, Dra. Alexandra Dinis, Enf.º Adélio Tinoco Mendes, Dra. Isabel Gomes, Dra. Isabel Ventura, Rev. Pe. Doutor Nuno dos Santos, Dr. Pedro Lopes, Doutora Teresa Lopa, Dra. Teresa Monteiro

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Appendix II- Informed consent for participants

This study, conducted as part of a master's academic thesis at the Faculty of Medicine of the University of Coimbra, aims to assess the educational effectiveness of a 3D simulation platform in invasive coronary angiography.

We kindly request your participation in this clinical study by completing a theoretical and practical evaluation, following an initial teaching session on invasive coronary angiography, ensuring that no one will know who responded or how they responded. The initial teaching session consists of a 1-hour theoretical lesson on invasive coronary angiography. Subsequently, students are randomized into two teaching methodologies, forming two groups (1:1). Group 1 views the 3D simulation procedure in a 20-minute video. Group 2 undergoes training on a 3D printed simulator (SimulHeart®), mimicking the standard invasive coronary angiography procedure for 20 minutes.

The assessment comprises a multiple-choice theoretical examination (scoring 0-100) and a practical examination conducted in the hemodynamics laboratory of CHUC, using SimulHeart®. The student's performance will be evaluated (scoring 0-100) at the time and after analysis of a video recorded by sub-specialists in Interventional Cardiology, according to a pre-established checklist. The practical part of the evaluation, conducted in the hemodynamics laboratory of CHUC, will involve exposing the students to a very low dose of ionizing radiation, for which all necessary personal protective equipment will be provided. For this reason, pregnant students should not participate in the clinical study.

The data obtained are completely confidential and will be used solely for the purpose of analyzing the variables of this study. Participation in this study and the established evaluation sessions implies consent for your responses and practical performance in the hemodynamics laboratory to undergo statistical analysis. This study has been approved by the Ethics Committee of the Coimbra Hospital and University Center (CHUC), ensuring the protection of the rights, safety, and well-being of all included participants, and providing public evidence of this protection.

I have read and agree to participate, having been informed about my concerns.

Signature of the consenting individual

____

Signature of the investigator

____

Appendix III- Theoretical multiple-choice exam (in Portuguese)

Identificação:

Nome: ____

1. Relativamente ao cateterismo cardíaco, é falso que:
   a. Está indicado no estudo etiológico da disfunção ventricular esquerda
   b. Permite identificar lesões coronárias, mas não a avaliação da sua gravidade.
   c. Permite a avaliação da gravidade da regurgitação aórtica
   d. Deve ser realizado de forma emergente nos doentes com Síndrome coronário agudo (SCA) com supra ST

2. Relativamente a radiação, é verdade que:
   a. A projeção radiológica é determinada pela posição da ampola/emissor relativamente ao doente.
   b. O detetor/intensificador deve estar o mais afastado possível do doente de forma a diminuir a radiação
   c. A ampliação da imagem é uma das técnicas que permite reduzir a radiação
   d. O uso de projeções mais extremas aumenta a radiação

3. Relativamente aos efeitos biológicos da radiação é falso que:
   a. O efeito determinístico é independente da dose de radiação
   b. O desenvolvimento de cataratas é um exemplo do efeito determinístico
   c. O uso de colete de chumbo, óculos de proteção e protetor de tiroide reduz a exposição à radiação
   d. O cancro é um exemplo de um efeito estocástico da radiação

4. Relativamente ao contraste usado no cateterismo cardíaco é falso que:
   a. O risco de nefropatia induzida pelo contraste é independente da taxa de filtração glomerular
   b. Pode causar reações alérgicas
   c. O risco de nefropatia de contraste aumenta com o volume de contraste usado
   d. Varia inversamente com a taxa de filtração glomerular do doente

5. Relativamente aos riscos associados ao cateterismo, assinale a afirmação falsa:
   a. O uso do acesso radial como acesso *default* permitiu a rápida deambulação mas não reduziu a taxa de hemorragia.
   b. Apesar de ser um exame um exame invasivo, a taxa de complicações graves é <1%.
   c. A nefropatia de contraste e alergia ao contraste são complicações descritas.

d. Durante o cateterismo, é obrigatória a monitorização invasiva contínua da pressão arterial.

6. Relativamente à anatomia coronária, é falso que:
    a. A dominância é determinada pela artéria que origina a artéria descendente posterior
    b. A coronária direita é responsável pela irrigação de 25-35% do VE
    c. <u>A dominância é esquerda em cerca de 80% dos casos</u>
    d. A coronária direita dá importantes ramos para irrigação do sistema de condução

7. Relativamente à anatomia coronária é falso que:
    a. <u>A artéria descendente anterior origina as artérias septais e obtusas marginais</u>
    b. A descendente anterior é responsável pela irrigação de ~50% do VE
    c. A circunflexa é responsável pela irrigação da parede lateral e posterior do VE
    d. As artérias diagonais são ramos da descendente anterior

8. Relativamente à canulação:
    a. A posição de canulação da coronária direita é obliqua anterior direita (OAD)
    b. <u>A posição de canulação da coronária esquerda e coronária direita é obliqua anterior esquerda (OAE)</u>
    c. A incidência lateral é uma das incidências *standard* do cateterismo diagnóstico
    d. Todas falsas

9. Em relação às projeções radiológicas, assinale a mais correta:
    a. A incidência obliqua anterior esquerda + caudal (*spider*) permite avaliação do tronco comum
    b. As incidências caudais permitem uma melhor avaliação da circunflexa e obtusas marginais
    c. As incidências craniais permitem uma melhor avaliação dos segmento médios e distais da descendente anterior
    d. <u>Todas verdadeiras</u>

10. Relativamente às projeções radiológicas, é falso que:
    a. Adicionar cranial a uma incidência esquerda permite uma melhor visualização da bifurcação da coronária direita na descendente posterior postero-lateral (crux)
    b. <u>A incidência obliqua anterior esquerda com caudal (*spider*) permite uma melhor separação da descendente anterior com as septais e as diagonais</u>
    c. A incidência cranial esquerda associa-se a maior radiação
    d. A incidência obliqua anterior esquerda com cranial permite uma melhor separação da descendente anterior com as septais e as diagonais

11. Em relação ao acesso radial é falso que:
    a. Pode ser realizado através de punção transfixiva *(abocath)* ou direta com agulha
    b. Menor risco hemorrágico comparativamente ao acesso femoral
    c. Maior risco de espasmo comparativamente ao acesso femoral
    d. <u>O cateter pode ser avançado diretamente sem a necessidade de guia em J</u>

12. Relativamente ao acesso radial, escolha a mais correta:
    a. A punção deve ser realizada com o punho em extensão
    b. A punção radial é realizada pela técnica de Seldinger
    c. A punção da artéria deve ser feita com a agulha a 30º- 45º.
    d. <u>Todas as anteriores</u>

13. Relativamente à canulação, escolha a verdadeira:
    a. <u>Em obliqua anterior esquerda (OAE), a coronária direita surge do lado esquerdo do ecrã e a coronária esquerda do lado direito</u>.
    b. Em obliqua anterior esquerda (OAE), a coronária direita e a coronária esquerda surgem do lado direito do ecrã.
    c. Em obliqua anterior esquerda (OAE), a coronária direita surge do lado direito do ecrã e coronária esquerda do lado esquerdo
    d. Todas falsas

14. A sequência habitual de estudo da coronária esquerda será:
    a. <u>OAE + caudal (*spider*) -> caudal -> OAD + cranial -> cranial 30º</u>
    b. OAE -> OAD -> <u>cranial 30º</u>
    c. Lateral -> OAE + caudal (*spider*) -> caudal -> OAD + cranial -> cranial 30º
    d. Nenhuma das opções anteriores

15. Relativamente à canulação da artéria coronária direita, qual a sequência correta:
    a. <u>Avanço de catéter JR 4.0 através do fio-guia 0.035'' até à raiz da aorta-> Remoção do fio-guia e purga do cateter -> Retirar catéter com rotação horária.</u>
    b. Avançar catéter JR 4.0 até à raiz da aorta sem fio guia -> Purga do cateter -> Retirar catéter com rotação horária.
    c. Avançar catéter JR 4.0 até à raiz da aorta sem fio guia-> Purga do cateter -> Retirar catéter com rotação anti-horária.
    d. Avanço de catéter JR 4.0 através do fio-guia 0.035'' até à raiz da aorta-> Remoção do fio-guia e purga do cateter -> Retirar catéter com rotação anti-horária do cateter

16. Relativamente à canulação da artéria coronária esquerda, qual a sequência correta:
    a. Avanço de catéter JL 3.5 através do fio-guia até raiz da aorta -> Remoção total do fio-guia -> Rotação anti-horária do cateter -> Purga do cateter.

b. Avanço de catéter JL 3.5 através do fio-guia até raiz da aorta -> Remoção parcial do fio-guia -> Rotação horária do cateter -> remoção total do fio e purga do cateter.
c. <u>Avanço de catéter JL 3.5 através do fio-guia até raiz da aorta -> Remoção parcial do fio-guia -> Rotação anti-horária do cateter -> Remoção do fio-guia e purga do cateter</u>
d. Avanço de catéter JL 3.5 através do fio-guia até raiz da aorta -> Remoção total do fio-guia -> Rotação anti- horária do cateter -> purga do cateter.

17. Relativamente aos cateteres, é verdade que:
    a. A utilização da via femoral habitualmente implica a utilização de um cateter Judkins esquerdo com uma curva mais pequena
    b. A angulação do tronco braqueocefálico não é um fator limitador do uso do acesso radial direito
    c. As dimensões da aorta ascendente não afetam a escolha do cateter
    d. <u>Todas falsas</u>

18. Relativamente à navegação dos cateteres até à raiz da aorta, assinale a afirmação falsa:
    a. <u>Devem ser avançados e retirados diretamente sem apoio de fio-guia, pois o fio-guia pode dissecar a aorta.</u>
    b. A navegação deve ser sempre “over the wire” com o fio guia à frente do cateter.
    c. A guia habitualmente usada para navegação é uma guia em J.
    d. Em trajetos tortuosos, fios guia mais hidrofílicos facilitam a navegação.

19. Na canulação das artérias coronárias
    a. Na manobra canulação coronária direita, escolhe a opção mais correta:
    b. Na canulação da artéria coronária direita, o cateter deve ser avançado ao longo da curvatura externa da aorta e fazendo injeções de contraste sucessivas.
    c. Na canulação da artéria coronária esquerda, o cateter deve ser avançado ao longo da curvatura interna da aorta e fazendo injeções de contraste sucessivas.
    d. Ambas verdadeiras
    e. <u>Ambas falsas</u>

20. Após a canulação, indique a sequência mais correta:
    a. <u>Purga do cateter -> avaliação da curva de pressão arterial-> injeção de contraste.</u>
    b. Injeção de contraste-> avaliação da curva de pressão arterial - > purga do cateter.
    c. Avaliação da curva de pressão arterial -> injeção de contraste -> purga do cateter.
    d. Nenhuma das opções.

21. Na troca de cateteres a sequência correta será:
    a. <u>Retirar o cateter do *ostium*-> avançar o fio guia em J até à raiz da aorta - > retirar o cateter mantendo fixo o fio guia.</u>

b. Avançar o avançar o fio guia em J até à ponta do cateter -> descanulação -> retirar o cateter mantendo fixo o fio guia
c. Retirar o cateter do *ostium* -> avançar o fio guia em J até à raiz da aorta - > retirar o cateter e o fio guia -> avançar novo cateter e fio guia.
d. Nenhuma das opções

22. Relativamente à segurança, assinale a falsa
    a. Quando há aplanamento da curva de pressão arterial devemos suspeitar da presença de ar no sistema
    b. Quando há ventricularização de pressões durante a canulação devemos suspeitar da presença de lesões ostiais
    c. <u>A purga de cateteres é obrigatória sempre após a canulação da coronária esquerda mas não da direita</u>
    d. A rotação excessiva dos cateteres pode causar o seu *kinking*

23. Relativamente à segurança, assinale a falsa
    a. A injeção seletiva na artéria do *conus* pode causar fibrilhação ventricular
    b. <u>Na ausência de curva de pressão arterial deve ser realizada injeção para identificar o problema</u>
    c. A injeção de contraste após uma canulação hiperselectiva pode causar disseção da artéria
    d. Quando há aplanamento da curva de pressão arterial devemos suspeitar da presença de *kinking* do cateter

24. Perante a presença de uma curva de pressões ventricularizada:
    a. Devemos suspeitar da presença de lesão ostial
    b. A administração de nitratos pode estar indicada
    c. <u>Ambas verdadeiras</u>
    d. Ambas falsas

25. Relativamente ao acesso radial, escolha a falsa
    a. A hemostase é frequentemente realizada com recurso a sistemas de compressão externos
    b. <u>Devido ao risco de oclusão radial, a hemostase é maioritariamente realizada com recurso a compressão manual.</u>
    c. A utilização de heparina reduz a incidência de oclusão da artéria radial
    d. A utilização de nitratos reduz a incidência de espasmo da artéria radial