Computer Simulation as Training Tool for Coronary Interventions

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13.1 Introduction

Interventional cardiology places high demands on cognitive and psychomotor skills of the operators. To optimize outcome and to minimize procedural risks, efficient training is mandatory. Current training programs traditionally rely on the "apprenticeship" mode of learning; the trainee acquires the skills by observing and imitating his mentor in the catheterization lab. Successively, the learner takes over the single steps of the procedure. Finally, starting with standard cases, he performs the whole procedure by himself under the auspices of his teacher, who intervenes only if mandatory.

Although this format will remain an essential part of catheter training, it is limited to establish a full-scale competency in catheter-based coronary procedures. Particularly, the adequate behaviour in non-routine und unexpected situations including complications cannot be systematically trained employing the apprenticeship mode of training. This classical learning experience is also poorly structured due to the huge cognitive background required for interventional decision making, mostly tacit mode of knowledge transfer, random admission of patients, and other factors. Therefore, additional training concepts designed to develop professional expertise and standards required for safe and efficient conduct of coronary interventions are necessary.

Simulation-based medical education has the potential to fulfill these needs [1]. Such education holds promise to improve basic interventional

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skills required for safety and efficiency of catheter-based interventions, crisis resource management (CRM) and team training in complex and highly demanding situations.

13.2 Rationale of Simulator-Based Training in Invasive Cardiology

From aviation, it is well known that simulation provides a well-defined environment for standardized and highly effective training [2]. Simulator training is mandatory for each pilot, starting from the selection process during recruiting over maintenance training up to special training required for handling new aircrafts.

In contrast to the long history of simulation in aviation, there is much less experience with simulation-based training in interventional cardiology. Nevertheless, the goals of simulator training in interventional cardiology and aviation are similar:

- Individualized learner-centered training programs
- Repetitive learning and formal feedback until proficiency is reached
- Training of rarely occurring and non-standard situations
- Learning from errors to provide long-lasting learning experience
- Increasing self-confidence to reduce stress level
- Repetitive and reproducible assessment of knowledge and skills in real-life-like scenarios

Virtual-reality simulators in interventional cardiology should provide a realistic hands-on training of the whole procedure comparable to flight simulation in aviation. By dedicated training of technical skills, procedural knowledge, decision making, and teamwork, the quality and safety of interventions should improve.

13.3 Virtual-Reality (VR) Simulators

Within the last 10–15 years, five virtual-reality simulators for coronary arteriography and interventions have been developed. They offer hands-on training with visual and haptic feedback.

Fig. 13.1 Pictogram of the C-arm, which virtually turns around the patient (ANGIO Mentor, Simbionix)

All systems provide manipulation of catheters wires, balloons, and stents and simulate real-time fluoroscopy, cineangiography, and hemodynamic measurements. Each system simulates a "C-arm" on the screen, which can be virtually rotated around the patient (see Fig. 13.1). All simulators have a foot switch for activation of cine and fluoroscopy. Some simulators have a special console with a joystick to steer the virtual C-arm (see Fig. 13.2). The additional instruments (syringe, indeflator) are either original or modified equipment according to the technical setup of the simulator. The interface device of the simulator is designed to sense the motion (push, pull, torque) of the inserted tools (guiding, balloon catheters, and wires). The forces applied are sensed by strain sensors. Translational positions and rotational angles are measured in real time and reproduced online on the screen.

VR simulation provides hands-on training of technical and cognitive skills. Identification of coronary artery stenoses using optimum projections is trained. Some of the simulators improve understanding of the spatial anatomy of the coronary tree by the aid of virtual views (3D views), which can be superimposed onto the standard 2D projectional coronary artery images. All five VR simulators have an arterial sheath already in place, thus, skipping the first procedural step, arterial puncture, and sheath placement.

Fig. 13.2 Steering console of a simulator (VIST, Mentice)

Procedural training is performed in a step-by-step fashion:

- Identification of the target lesion
- Selection of a guiding catheter and intubation of the coronary artery
- Preparation and advancement of the guidewire across the target lesion
- Selection, sizing, introduction, and positioning of the instrumentation (balloon, stents)
- Handling of impediments and management of complications

At the end of the procedure, all simulators provide comprehensive metrics for the assessment of the procedural outcome and trainee's performance.

13.3.1 VIST (Mentice)

VIST is a virtual-reality simulator, which provides catheter training for coronary and peripheral interventions. VIST-C is the portable version of the VIST system (Fig. 13.3). Each simulated case is built up from real MR, CT, or angiographic data. The teach-

Fig. 13.3 VIST-C (Mentice)

Fig. 13.4 Simulated angiographic image and hemodynamics (VIST C)

ing cases contain demographic data, clinical presentation (incl. ECG), and current medications.

The simulator has a special module for coronary arteriography performed either via a transfemoral or transradial approach. The latter includes challenging anatomical variants of the brachial artery such as narrow lumina and vessel loops. Uncontrolled catheter and wire movements may cause typical complications such a spasm and dissection.

The module Coronary PRO is an advanced training module for coronary intervention providing simulations at different skills levels, ranging from standard cases to complex scenarios such as acute myocardial infarction, cardiogenic shock, and chronic total occlusion. Furthermore, Coronary PRO simulates complications such as distal embolization, no reflow, spasm, perforation, and dissection. These complications have to be assessed and resolved to finalize the case. The module incorporates vital signs that respond in a dynamic fashion to given angiographic settings, actions, and reactions of the trainee. For example, following a deep insertion of the guiding catheter dampening of the pressure curve occurs. The trainee is expected to reposition the guiding catheter. Training of two-wire procedures implemented for example in bifurcation stenting is also possible using a special bifurcation system (VIST® Dual).

The additional non-coronary training features include peripheral interventions, intracerebral interventions, carotid stenting, resynchronization therapy, endovascular aortic repair, and transseptal puncture.

Advantages and drawbacks of the VIST system include:

Advantages

- Lifelike images from the coronary tree and the surrounding tissue (bone, lung) (Fig. 13.4)
- Usage of real-life instrumentation
- Realistic vital signs (aortic pressure curves, ECG, heart rate, oxygen saturation)
- Autotrack function, which adjusts the virtual table to the most distal tool avoiding manual adjustments of the table

Drawbacks

- Unrealistic movements of the Judkins guiding catheters, potentially resulting in intubation of the right and the left coronary artery with either of the two types of the catheter

13.3.2 ANGIO Mentor (Simbionix)

The ANGIO Mentor is available in two versions: The ANGIO Mentor Ultimate is a stationary unit, whereas the ANGIO Mentor Express is a small-sized mobile system (Fig. 13.5). Several virtual cases created from CT images of real patients are available for coronary arteriography and interventional procedures. The system features vital signs simulation including heart rate, systolic/diastolic blood pressure, and electrocardiogram. Drug administration is possible, and responses of vital parameters can be simulated.

Complications such as dissection or perforation are implemented and can occur

Fig. 13.5 ANGIO Mentor (Simbionix)

following inappropriate maneuvers with the guiding catheter or over-sized balloon dilatations. Complications must be properly handled for cases to continue.

Beside coronary angiography and coronary intervention, several other non-coronary modules are available: carotid interventions with distal protection, renal interventions, peripheral interventions, abdominal aortic aneurysm repair, cerebral angiography, and intervention catheter-based aortic valve replacement (CoreValve) and cardiac rhythm managements including right ventricular resp. coronary sinus pacing and AF ablation.

Advantages and drawbacks of the ANGIO Mentor system include:

Advantages

- Coronary images with realistic appearance (Fig. 13.6).
- Anatomically correct aortic root with all three sinuses.
- Multiple complications with realistic appearance such as dissections and perforations.

Drawbacks

- Program errors allow easy, but unrealistic balloon catheter advancement into the coronary artery despite guidewire looping in the aorta (Fig. 13.7).

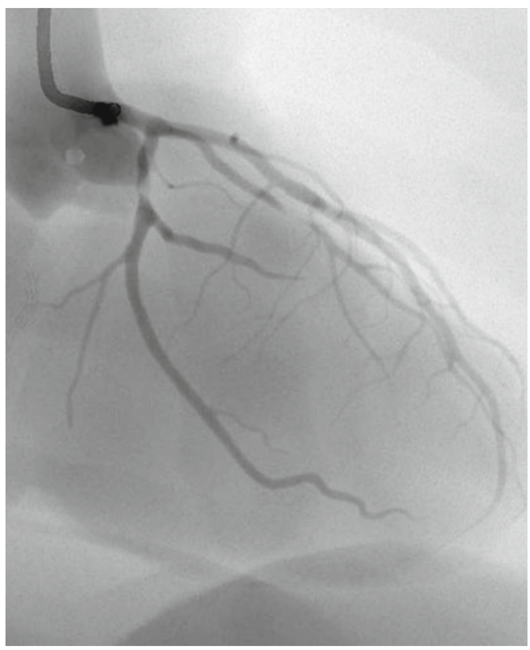

Fig. 13.6 Simulated angiographic image (ANGIO Mentor)

- Peripheral loop formation of the wire (due to the underlying "graphical" force feedback).
- The plunger of the syringe is armed with a detector to recognize the dye injection, a design prone to technical failure.

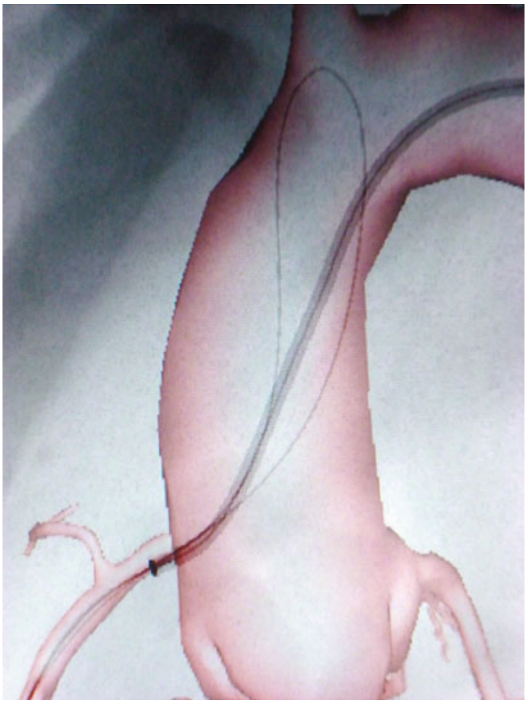

Fig. 13.7 3-D-image of the aorta demonstrates an unrealistic balloon catheter advancement into the coronary artery despite guidewire looping in the aorta

13.3.3 SimSuite (MSC)

SimSuite is part of a realistic computer-based training system (CBT) that trains decision making, hand-eye coordination, catheter selection, and handling (Fig. 13.8). The CBT includes a clinical case presentation and a short self-test with immediate feedback. Catheters and guidewires can be manipulated as they enter the interface device that tracks their motion through a series of electromechanical sensors. A variety of serious adverse events is implemented allowing a training of their treatment.

Advantages and drawbacks of the SimSuite system include:

Advantages

- Lifelike vascular anatomies
- Cath-lab-like setup with several monitors
- Comprehensive user feedback with metrics

Drawbacks

- Stationary non-mobile system and necessity of special balloons catheters, stents, wires and indeflators as substitutes of the real devices

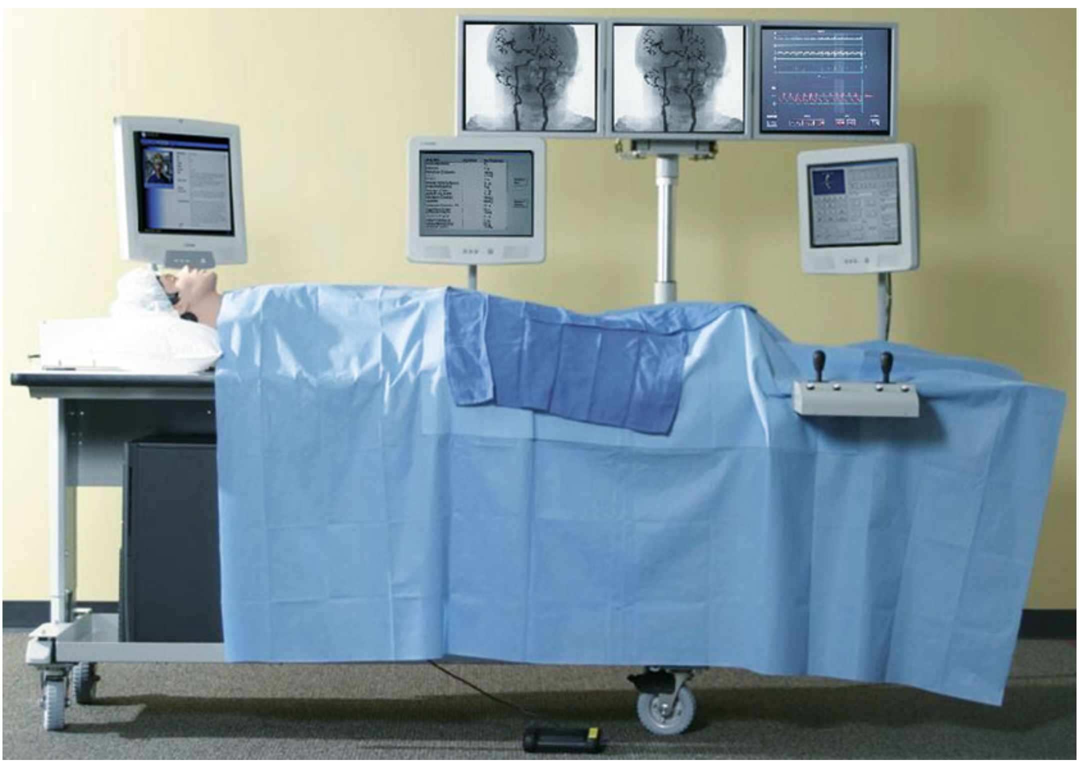

Fig. 13.8 SimSuite (MSC)

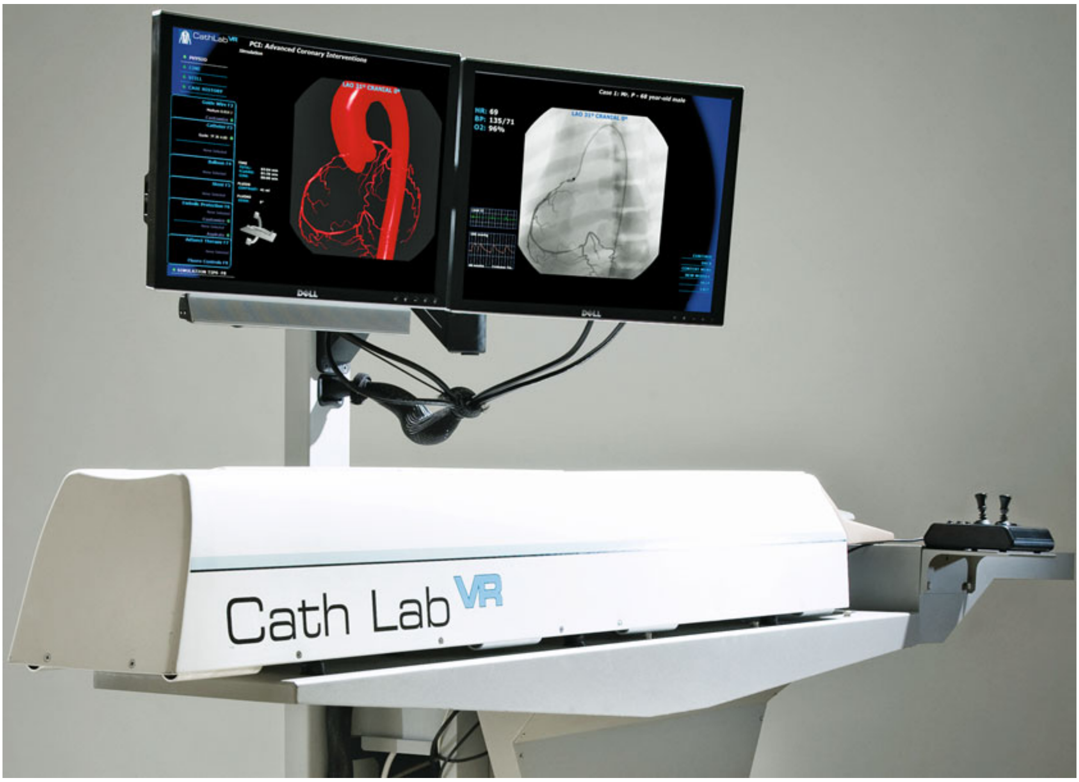

Fig. 13.9 Cath-Lab VR (CAE Healthcare)

13.3.4 Cath Lab VR (CAE Healthcare) (Fig. 13.9)

The basic PCI software contains ten cases with single- or multiple-vessel coronary disease. These cases reveal increasing difficulty and familiarize the trainee with basic angiographic techniques to visualize the coronary anatomy. The advanced PCI software includes ten cases of challenging coronary anatomy that include treatment of acute myocardial infarction, saphenous vein graft stenoses, chronic total occlusion, and ostial and thrombotic lesions. Complications have to be adequately treated for continuing the case; each complication will be recorded for final review.

The force feedback of the system mimics a realistic look and feel of coronary diagnostic and intervention. The trainee is exposed to forces encountered during crossing of stenosis with the balloon catheter, respectively, the stent. Wrong selection of guiding catheters or inadequate intubation of the coronary artery can result in dampened pressure. Additionally, the simulator gives auditory feedback. In acute myocardial infarction, the virtual patient may complain about pain, which should prompt adequate pharmacological, e.g., administration of morphine, nitroglycerine or adenosine, and interventional treatment. Furthermore, the virtual patient's complains about pain may get louder accounting for a real-life scenario and putting the trainee under emotional stress, thus, stepping up the challenge of the intervention. It is one of the teaching aims, to develop a host of mental abilities such as empathy for the patient, stress resistance, and focal attention of the trainee under pressure in challenging case scenarios [3].

The simulator also has additional non-coronary features including carotid artery angioplasty

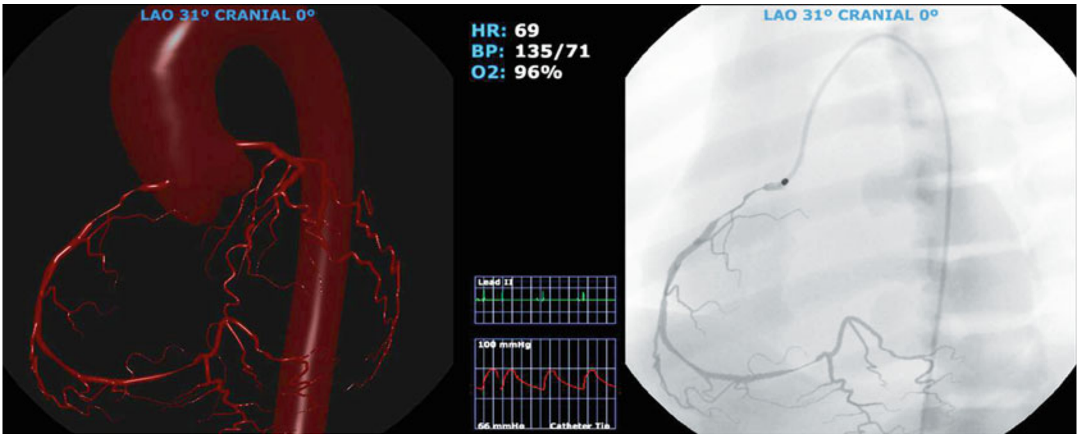

Fig. 13.10 Simulated angiographic view (right) and corresponding 3-D-image (Cath-Lab VR)

Fig. 13.11 CATHIS mobile (CATHI GmbH)

with embolic protection device, transcatheter aortic valve implantation (TAVI), and a training program for lead placement in the coronary sinus, a component of cardiac resynchronization therapy.

Advantages and drawbacks of the Cath-Lab VR system include:

Advantages

- Realistic force feedback
- Highly educative 3D simulation of the coronary tree (Fig. 13.10)
- Four carriages for insertion and rotation of up to four instruments simultaneously

Drawbacks

- Large-size simulator, which makes combination with a mannequin on a catheter table difficult

13.3.5 CATHIS (CATHI GmbH)

CATHIS and its mobile version, CATHIS mobile (Fig. 13.11), provide virtual cases, which have been created from angiographic images of real patients. Procedural training may either focus on basic skills (navigation of guidewires, selection and positioning of balloon catheters and stents) or on more complex

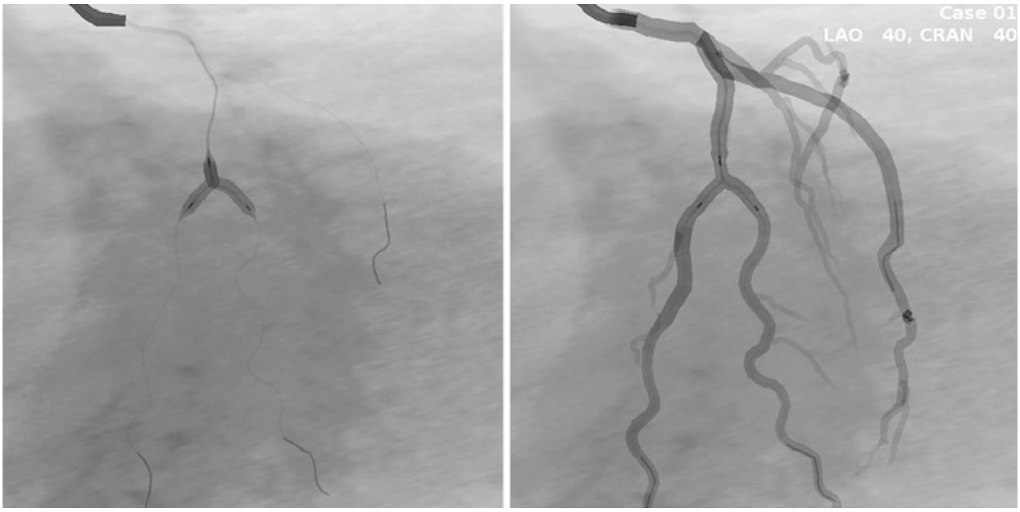

Fig. 13.12 Simulated angiographic images (CATHIS) of kissing balloon dilatation

aspects (bifurcation stenting, complication management). Kissing balloon techniques can be performed by using two wires and two balloons (Fig. 13.12). Different sort of complications such as coronary perforations, dissections, thrombus, and spasm have been programmed based on elastomechanical models. Their occurrences are triggered by mechanical stimuli, which cross a predefined threshold (e.g., force on a vessel wall).

Additionally, training modules for intracoronary ultrasound, intra-aortic balloon pump, or circulatory support systems such as Impella and Pulsecath are available.

Advantages and drawbacks of the CATHIS system include:

Advantages

- Simulated contrast injection can be performed with fluid instead of air.
- The system can be linked to a proprietary angiographic catheter unit (Artis Zee, Siemens).
- Real catheters (balloon catheters, aspiration catheter) can be used.

Drawbacks

- No force feedback.
- No virtual 3D images

13.4 Virtual-Reality (VR) Simulation in PCI

13.4.1 Tool Selection According to the Learning Goals

The multiple steps of percutaneous coronary interventions (PCI) can either be exercised on simple plastic models or on more sophisticated VR simulators. For example, the first step of the procedure, arterial puncture with sheath placement, is a very standardized task, which can adequately be trained on low-tech mechanical models such as Simulab (Simulab). In contrast, coronary arteriography is more complex. Therefore, VR simulation is an adequate training tool, because it facilitates the understanding for case-adjusted catheter selection and handling. For example, in a case with enlarged aorta or high take-off of the right coronary artery, VR simulation (with the adjunct of 3D imaging) can help to understand the underlying anatomy and, thus, to perform the adequate catheter selection. Furthermore, finding of best angiographic views to recognize and quantify coronary stenoses can be trained. Finally, the dynamic metrics of the simulators can help to objectify the psychomotor performance of the trainees.

For coronary intervention, several mechanical training models are available. For example, advancement of the guide and the balloon catheter can be trained on the pulsatile model CoroSim under fluoroscopic guidance (Mecora Medizintechnik GmbH). However, the potential of this type of mechanical training tool is limited, because it does not provide a variation of the underlying anatomy.

In contrast, VR simulators allow the selection of different cases with variable severity of the underlying coronary artery disease, single vs. multiple vessel disease, or stenoses with and without calcification. The most adequate interventional technique for each case such as primary stenting, bifurcation stenting, simple balloon angioplasty, and others can also be trained.

Combination of highly sophisticated VR simulators with mechanical models can be useful to simulate complex interventional procedures ("hybrid simulation"). To train the management of catheter-induced cardiac tamponade in the cath lab, we developed a "hybrid simulator," which combines the VR simulator CATHIS (CATHI GmbH) with a modified mechanical pericardial puncture model (KOKEN CO.) [4]. Cardiac tamponade due to coronary perforation requires urgent endovascular closure of the leakage site (either with a balloon or a covered stent) and expert pericardiocentesis. Both procedures can be trained on this hybrid simulator. During PCI training on the VR simulator, type III perforation occurs under certain circumstances such as oversized balloon dilatation or stenting. In these rare cases, rapid balloon dilatation has to be performed proximal or at the site of the vessel perforation followed by implantation of a covered stent. In case of a delayed closure of the leakage, aortic pressure drops as a sign of cardiac tamponade. Under these circumstances, immediate pericardiocentesis is indicated, which can be performed at this model with a real puncture needle. When the needle enters the "pericardial space," red fluid can be aspirated. Withdrawal of "blood" results in recovery of the aortic pressure and stabilization of the critical situation.

This hybrid model teaches rapid decision making, skilled catheter handling, and pericardiocentesis and is an example of how different learning modules can be combined to train complex treatment modalities in interventional cardiology.

Team training for diagnostic and interventional coronary procedures requires a combination of a VR simulator and a full-scale mannequin (Fig. 13.13). All five VR simulators for coronary interventions can generally be combined with a full-scale simulator on an examination table. However, for this purpose, CATHIS mobile, ANGIO Mentor, and VIST-C are especially useful due to their compact size. Schütz et al. [5] connected CATHIS with the full-scale simulator HPS (METI, Sarasota, FL) and synchronized the heartbeat between the two simulators, which provided a highly realistic scenario for CRM training in interventional cardiology.

13.5 Simulation-Based Training: Role of the Trainer

Virtual-reality training in interventional cardiology is not useful without proctoring. Simulator training, without expert trainers, carries the risk of adapting wrong habits and should be avoided.

Ideally, the trainer should be an experienced interventional cardiologist and a dedicated teacher in one person. Under these circumstances, maximal benefit can be achieved from simulation-based training [6]. If the proctor understands the potential and limitations of the simulator and knows the selected training cases, he can use the simulator as an optimal platform for highly efficient and long-lasting transfer of procedural knowledge and technical skills. The mentor creates the clinical context and explains the procedural decision making. He should also give advice on certain technical skills and can take over the handling of the catheter devices to demonstrate tips and tricks for better performance while avoiding technical errors and mistakes during the procedure.

To achieve the maximal effect of simulation-based catheter training, "train the trainer" programs for proctors are recommended.

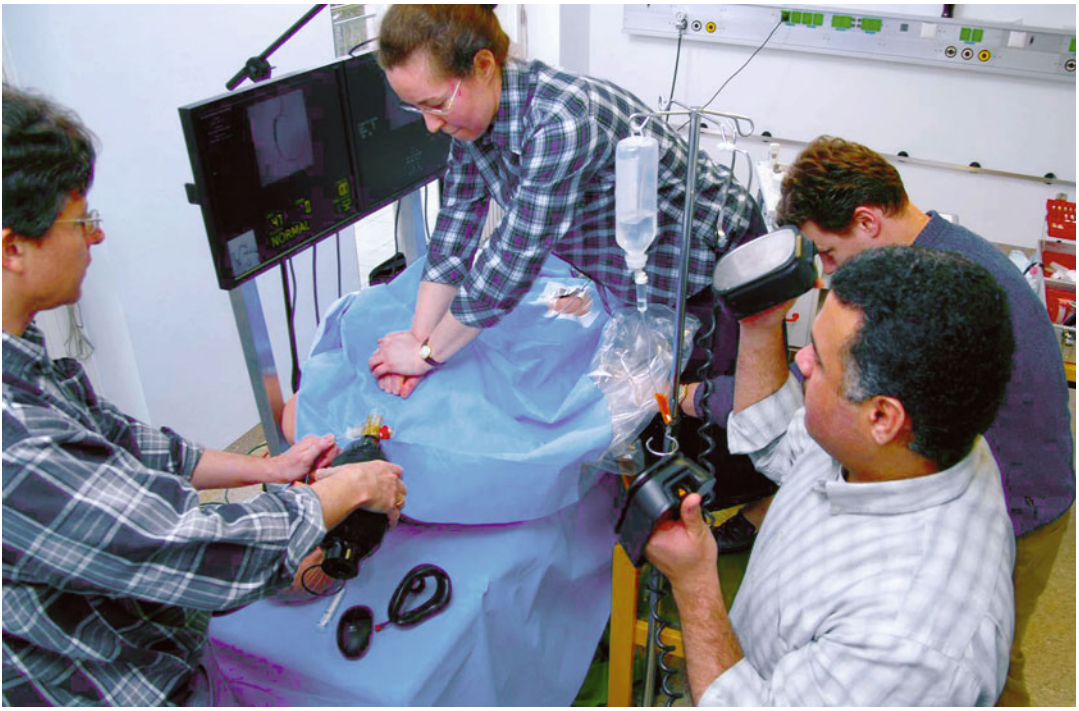

Fig. 13.13 CRM-training on a VR-simulator linked to a full-scale mannequin

13.6 Curriculum-Based Simulator Training in Invasive Cardiology

An underlying curriculum with clearly defined learning objects should help to decide which simulator is most adequate for which training course. The curriculum should determine the selection of the simulators and not vice versa.

VR simulation can be either used for task training (coronary arteriography, percutaneous coronary intervention, transcatheter aortic valve implantation) or for CRM training in conjunction with a full-scale simulator. Depending on the learning target, simulation will either be restricted to task or to CRM training. In most courses, however, simulators will be used for both applications.

The working group AGIK (**A**rbeits **G**emeinschaft **I**nterventionelle **K**ardiologie) of the German Society of Cardiology published recommendations for the content and structure of simulator-based courses in interventional cardiology (http://www.agikintervention.de/; available in German language only at present). In this publication, three task levels for simulation-based training have been defined (Table 13.1): Level I introduction into coronary arteriography, Level II introduction into percutaneous coronary procedures, and Level III advanced courses including bifurcations, chronic total occlusion, and interventions in acute myocardial infarction. The adequate use of simulators on the different levels is described in these recommendations.

Additionally, a level IV is defined, which runs in parallel to levels II and III courses and focuses on crisis resource management and team training.

Table 13.1 Structured course concept: "The AGIK-quality criteria for simulation-based training courses in interventional cardiology"

Level III: PCI-advanced courses[a]	*Level IV*: CRM-course (Team-training)
Level II: PCI-introduction	
Level I: Coronary arteriography-introduction	

www.agikintervention.de/

[a]Acute myocardial infarction, bifurcation lesion, transradial intervention etc.

In general, simulation courses are performed on 1–2 days in small groups (up to 15 participants). Seventy percent of the course time should be reserved for hands-on training or case discussions. Time for lectures is restricted to 30% of the course. At least two VR simulators and different mechanical models should be available for this type of simulator courses.

The trainee should have basic knowledge about the anatomy of the coronary circulation and the pathology of coronary artery disease before starting the training on the simulator. Furthermore, the trainee should know the steps of the procedure to be learned and the principles of radiation protection.

13.6.1 Simulation Based Task-Training (Level I–III)

After a short introduction about the simulator and the usage of the control devices (console and foot switch), the proctor explains the simulation software to activate the different tools (guide catheter, wire, balloon, stent) and the handling of these devices.

Then, the preselected cases are discussed. Based on the patient's history, the symptoms and the ECG findings, the trainees have to decide about the treatment strategy: (1) indication for PCI vs. conservative treatment or surgery, (2) successive steps of the intervention, and (3) treatment modalities: wire selection, primary balloon dilatation or stenting, and stent type (drug-eluting stents vs. bare-metal stents and sizing).

According to the abovementioned recommendations, maximal 2–3 learners should be trained by a single proctor. In general, one trainee takes over the role of the first interventionalist, and the second trainee assists, whereas the third trainee (if present) takes over the role of an active observer, who is fully involved in the decision-making process. The three trainees rotate, such that each of them gets the same amount of hands-on experience.

13.6.2 Simulation-Based Team Training and Crisis Resource Management (Level IV)

PCI carries a certain risk of major complications. Training is mandatory to prepare interventionalists for proper management of these critical events. From aviation, it is well known that simulation-based training of crisis resource management is useful to reduce errors in the highly demanding situations of emergencies. The importance of teamwork in preventing medical error is also well recognized, and simulator-based team training has been advocated as a possible preventive approach [7].

Task training together with full-scale simulation can provide an optimal platform to prepare teams for emergency situations in catheterization laboratories. According to the abovementioned guidelines, up to six participants can be trained in a CRM session on a VR simulator combined with a full-scale mannequin. During this type of sessions, the proctor is generally supported by a technician, who operates the full-scale mannequin and triggers the events at certain time points in close agreement with the proctor (e.g., induction of AV block III after reopening the right coronary artery in acute myocardial infarction). After the end of each scenario, the proctor gives a structured feedback. For this postprocedural review, video documentation of the life session is a useful tool and therefore highly recommended. The personal interaction of each participant within the team, guidance, communication, and decision making should be systematically analyzed, possibly by the aid of a psychologist with expertise in human cognition.

13.7 In Situ Training

Simulation-based education can be performed in dedicated medical training centers or in a real catheterization laboratory. If the training is performed in the catheterization laboratory of the participants, it is called "in situ training". "In situ training" provides the most realistic environment for CRM training, because team performance, e.g., the specific roles in emergency situations, the setting (location of screens, defibrillator, and others), and the full range of equipment can be tested and employed for training. For this purpose, the combination of VR simulator and a full-scale mannequin is placed together on the cath-lab table. It is most advantageous, if the simulated X-ray images and pressure and ECG curves can be shown on the associated monitors of the cath lab. The CRM training with the different scenarios is guided by a proctor. Debriefing is performed with the aid of video documentation.

13.8 Study Results

Simulation-based training can improve surgical performance in the operating room; this important insight has been demonstrated in a number of studies employing surgical simulators [8–10]. Chaer et al. [11] performed a randomized study in 20 patients and could demonstrate that a short (2 h) simulator training on the VIST simulator significantly improved the endovascular skills (iliac angioplasty and stenting) in the "simulator" group. Similarly, it has been shown in another small study that VR-simulator training can also improve skills in carotid stenting [12]. Additionally, a positive effect on the learning curve with improved performance of carotid angiography was demonstrated for the VIST simulator [13]. Recently, a validation study of the same simulator revealed the superiority of simulator-based training compared with conventional training in the performance of transseptal catheterization [14].

However, to date, no studies are available to document the effect of simulation-based catheter training in interventional cardiology. Our group currently performs a randomized study to answer the question if catheter-based training on different simulators may be superior to conventional training with regard to skills acquisition and knowledge transfer in novices of interventional cardiology.

13.9 Future Development

Simulation-based training in interventional cardiology provides an excellent hands-on practical procedural experience and holds promise to improve retention of skills and transfer of knowledge compared to conventional learning. Training centers provide lifelike simulation fulfilling the mission to create a safer environment for patients and to contribute to the education of future generations of interventionalists.

Nevertheless, availability of experienced and dedicated proctors, who use the simulator as a platform to transfer their knowledge and skills, is the most critical factor to achieve the optimum teaching effect of simulation-based training in interventional cardiology.

However, several limitations of the presently available virtual-reality (VR) simulators have to be solved before a broad dissemination of simulation-based training may take place in interventional cardiology. Foremost, more realistic technical equipment and better images allowing close imitation of real-life cases are required. Presently, each of the available simulators has certain software limitations accounting for freak errors such as the movement of the guidewire tip beyond the vessel border. General drawback of all simulators is their steering box, which does not resemble marketed consoles, neither in design nor function. Thus, the acquired knowledge to handle the simulator in this context cannot be transferred into the daily routine.

Highly sophisticated and costly simulators will not play a future role in regular and continuous training programs, especially when handling remains difficult, technical failure rate high and application specialist necessary to run the system. For a widespread use, simulators must change to affordable, ready-to-use systems, which can easily be connected to the hardware equipment in the cath lab or a training center.

Comparable to aviation quality programs in the catheterization laboratories will turn mistakes and errors (misses and near misses) into training scenarios to prevent and manage similar incidents in real life in the future.

Additionally, procedural rehearsal could be an entirely new way to use simulation for enhancement of safety. Based on the patient's CT data, an individual simulation of the anatomy, pathology, and procedural challenges can be built and loaded into the simulator for prior training of the real cases [15].

Simulation already has the potential for assessment of technical and cognitive skills of physicians performing coronary interventions [16]. This range of application will be extended, based on advances in VR technology and broader clinical application.

Conclusions

In summary, we suggest that:

- Simulation has already become a very effective tool for task and CRM training in interventional cardiology. Based on our experience, novices benefit most from the VR training.
- Despite notable differences in the design, the presently available VR simulators provide a realistic representation of a limited scope of clinical scenarios.
- However, randomized control studies are still lacking providing scientific evidence that catheter-based procedures can indeed enhance the quality of performance in patients, a formidable task for the entire interventional community.

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