Three-Dimensional Simulator: Training for the Novices in Embolization With Liquid Agents

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Abstract

Background: To design the simulator for novices without prior experience in embolization with liquid agents such as n-Butyl cyanoacrylate (n-BCA) and to evaluate the simulator using surveys and post hoc video analysis.

Materials and Methods: The simulator was created using computer-aided design software and three-dimensionally printed. Before an embolization, trainees had filled the questionnaires regarding their level of expertise and self-reported confidence level. The participants were divided into the novice or the expert groups, were shown an instruction video, and each performed four embolizations. Subsequently, they completed the surveys on self-reported confidence level and assessed the simulator's face and content validities.

Results: 5 experts and 12 novices trained on the simulator. The experts were radiology fellows with at least five years of work experience. The novices were medical students and radiology residents in postgraduate years one and three, without any previous experience with embolization. Based on the surveys, the experts assessed the simulator as very useful for embolization training. Performance, e.g. mean duration embolization between experts (mean $\pm$ standard deviation = 189 ± 42 seconds) and novices (mean $\pm$ standard deviation = 235 ± 66 seconds) were significantly different ($p = .001$). The embolization, simulated complications, and educational capabilities of the simulator were evaluated positively. The self-reported confidence level rose by a mean of over two points, using the 5-point Lickert scale, in the novice group ($p < .001$).

Conclusion: The liquid embolization simulator is an educational tool, mimicking embolization. It reduces the duration of embolization and improves the confidence level of the novices significantly.

Background:

Simulation training is an educational standard in many different areas of the aviation industry. Aircraft pilots train and need to demonstrate their skills on certified flight simulation training devices [1]. In recent years simulation is gaining more and more attention in medical education and training. For example, emergency response units use simulation, to prepare and adapt to changing working environments [2]. In radiology, simulators are used to enhance procedural and non-procedural skills [3]. Simulation-based training is already today a recommended or required part of some residency programs (vascular surgery, interventional cardiology, neurosurgery) [4]. One important reason for this development is the shortage of training opportunities. Since the advent of computer tomography and magnetic resonance imaging-based angiography, there is a lack of "easy training cases" especially in the field of interventional radiology (IR) [5]. IR encompasses a broad spectrum of interventional procedures, including embolization. Embolization with liquid agents has become a widely used treatment for arteriovenous malformations, varicoceles, gastrointestinal bleedings, aneurysms, and pseudoaneurysms [6]. Those procedures require advanced haptic skills, knowledge of the subsequent steps, and a proper risk assessment. In the field of

IR, there is an increasing interest to use simulation-based training, especially for enhancing procedural skills for vascular intervention [3]. The simulators can be classified into three categories of models: animal models, physical models (e.g. tube models), and virtual reality (VR) simulators [7]. They offer a distinctly unique training experience, prioritizing various characteristics of the simulation.

The animal models offer a few embolization objectives [8, 9]. They provide realistic haptic feedback, but come with many ethical concerns, are costly, non-reusable, and preparation of a training environment is complex [7]. The VR-simulators offer various scenarios (e.g. peripheral embolization), can be repeatably used, and objectively assess trainees' performance [10]. Their significant disadvantages are relatively high purchasing costs, regular maintaining services, and expensive repairs [7]. Another important disadvantage of most VR-simulators is the absence of liquids, resulting in inadequate depiction of injection-rates and the handling of air bubbles.

In comparison, physical tube models are cheaper and can be used intuitively, without prior training on a training system itself. They allow training of interventional procedures using real instruments and materials with realistic haptic feedback. The main restriction of these models is a limited amount of vascular anatomy and pathology, simulated in one specific model [7].

To our knowledge, no physical model for embolization procedures with liquid agents is commercially available. Therefore, we wanted to create a model, capable of teaching fundamental procedural steps of the embolization procedure. The model, mimicking the embolization with such solutions, should provide a realistic training environment while being low-cost and open up for a possibility of one-time use models. To achieve a high educational validity of the simulator we followed these steps: 1) defined learning objectives by interviewing IR experts, 2) developed the physical model, 3) evaluated our model in a training by the novices and the experts in IR.

Materials And Methods:

Learning objectives: The learning objectives were defined and based on interviews with three IR experts with numerous years of clinical practice. The interviews consisted of questions regarding steps of embolization, used instruments, characteristics of embolic agents, and accompanying complications. The answers were collected and precise learning objectives were defined, forming a foundation for the development and the evaluation of the simulator.

Model construction: The model was sketched, sculpted, and exported as a stereolithography (STL) file using Autodesk Fusion 360 (Autodesk Inc., San Rafael, California) and further modeled in Meshmixer (Autodesk Inc., San Rafael, California). The sculpture was imported to Preform (Formlabs Inc., Somerville, Massachusetts), printed on Formlabs Form 2 (Formlabs Inc., Somerville, Massachusetts), and cured using ultra-violet light with Form cure (Formlabs Inc., Somerville, Massachusetts). The model consists of four chambers with adjacent collaterals, interconnected between one another by a network of tubes. The chambers are in the shape of cylindrical segments in a volume of two or three milliliters to sensitize trainees to various quantities of a required embolic agent. The design incorporating various chambers

should mimic vascular pathologies such as arteriovenous malformations or highly vascularized tumors. At the top are cube-shaped blocks filled with a sponge. They act as a filter, blockading the flow of embolic agent outside of the model. The three outflows are united into a single outflow with the additionally printed adapter. After embolization of all the chambers, only the main component needs to be replaced, while the adapter can be repurposed (Figure 1). The model has a size of 149 x 119 x 21 mm and it takes approximately 7 hours and 45 minutes to print. This design purposely depicts abstract targets (chambers) and not specific anatomical regions. It ensures the possibility of embolization training for various endovascular subspecialties e.g. interventional radiology or neurosurgery.

Model evaluation: We wanted to evaluate our model by the two groups: experts and novices. We have defined the experts as fellows in radiology with at least five years of work experience. The novices were medical students or radiology residents with no prior experience with embolization. Every participant had to perform four embolizations. Participants should identify the given targeted chamber, place the catheter and guide wire in a controlled manner into the predetermined chamber and adjust the necessary amount of embolic agent. The injected amount should be equal to two or three milliliters, depending on the targeted chamber. To approach the chamber 0,035" angled guide wire (Terumo, Tokyo, Japan) and a 0,038" angiographic catheter (Cordis, California, USA) were utilized. The simulator was connected to a flow pump (FlowTek 100, United Biologics Inc., Santa Ana, California). Underneath the simulator, a LED panel was placed to increase the visibility of all materials. A camera above the simulator was used to record the training and connected to a laptop for visual feedback. The setting ought to simulate an angiographic suite, where two-dimensional images are translated into the three-dimensional (3D) space (Figure 2 and 3). To replace the embolization agent, we tested different materials. For this purpose, we used the following selection criteria: 1) the material should behave plastically when applied, 2) it should harden after application and form a solid body, 3) the material should be non-toxic, 4) it should be widely available. Based on the selection criteria, we identified superglue as an appropriate agent. By comparing viscosities and densities of selected superglues with n-BCA and considering their availability, we decided to use Pattex superglue liquid (Henkel AG & Co, Düsseldorf, Germany) as our primary agent. The training area of the simulation was divided into "dry" and "wet" areas. In the dry area, participants prepared an embolic agent, where they mixed Pattex Superglue Liquid with red paint pigment for better visibility. In the wet area, the embolic agent was delivered via three ml syringes. To substitute a contrast agent, we chose blue food coloring. To evaluate participants' effectiveness and measure the time of procedures, we used two cameras: one directly above the simulator and the second one pointed at the participants. The number of occluded chambers, backflow instances, and embolization time were assessed with post hoc video analysis. The occlusion was a success when the embolus closed the chamber, with no observable flow of the contrast agent in the control phase. The backflow was defined as reflux of the embolic agent, resulting in a closure of the collateral vessel and blockage of a contrast agent's flow. The time of embolization was measured from the moment of the catheter's introduction through the sheath until retraction of all materials. Additionally, all participants filled out a questionnaire evaluating the simulator and the overall training.

Statistical analysis: The number of closed chambers and backflow of the embolic agent were compared between the groups using a chi-quadrat test. The duration of embolizations between the groups was analyzed using an independent samples Student's t-test. The evaluation of tasks, complications, and educational capabilities were summarized in the table. The changes in proficiency level before and after the training in both groups were compared using the paired samples Student's t-test. In the analysis, we have used SPSS (IBM, Chicago, Illinois) and GraphPad Prism (GraphPad, Software, San Diego, California).

Results:

Learning objectives: Based on the interviews, the following learning objectives were defined: 1) handling and navigation of catheter and guidewire, 2) preparation and application of embolic agent, 3) embolization of given target, 4) occlusion's control with contrast agent and 5) awareness of arising complications, such as catheter's gluing, insufficient occlusion, backflow, collaterals' and wrong vessels' occlusion.

Model construction: To construct the simulator, we have thought of a rather abstract network of tubes with interconnecting chambers. Each chamber acted as the target of embolization. The model was designed in a 3D modeling software, i.e. Autodesk Fusion 360 (Autodesk Inc., San Rafael, California) and further modeled in Meshmixer (Autodesk Inc., San Rafael, California). The model was then printed on a 3D printer, i.e. Formlabs Form 2 (Formlabs Inc., Somerville, Massachusetts), and cured using ultra-violet light with Form cure (Formlabs Inc., Somerville, Massachusetts).

Model evaluation: The study involved 17 participants: 12 novices and 5 experts. Three embolizations in the novice group were excluded from the measurement, as they were disturbed by glue residues blockading the vessel or incorrect application of the embolic agent. To test the educational validity of the simulator, we compared the performance of the experts and the novices. In the post hoc video analysis, we were focused on the number of occluded chambers, backflow occurrence, and duration of embolization. The experts occluded 18 (90 %) chambers and the novices 36 (80 %) ($p = .321$). The backflow of the embolic agent could be prevented during 19 (95 %) embolizations in the expert group and 39 (84,4 %) in the novice group ($p = .232$) (Figure 4).

To test the training capabilities of the simulator, we have measured the duration of each chamber's occlusion. The mean times of embolization were at 189 ± 42 (mean $\pm$ standard deviation (SD)) seconds within the expert group and 235 ± 66 (mean $\pm$ SD) seconds within the novice group ($p = .001$). The measurements split into the individual chambers are depicted in Figure 5. The duration of the embolization was reduced between the first and the fourth occluded chamber by 56 seconds in the expert group and 37 seconds in the novice group.

To evaluate the realism of our simulator, we asked the experts and the novices about trained tasks and complications (Table 1 and 2). To assess the simulator's training potential, we asked the experts, if our model could be used as a training tool (Table 3).

The self-reported change in the performance and knowledge illustrates the level of confidence of the trainees. They were evaluated matching the mean answers to the identical questions regarding the proficiency level, before and after the training. The novices exhibited significant differences in the outcomes. The mean difference was at 2,1 ($p < .001$) (Table 4). The experts did not show significant differences.

Discussion:

The aim of this study was the construction and evaluation of the physical embolization simulator. We defined the learning objectives by interviewing the IR experts, constructed the simulator, and evaluated it through the surveys and the post hoc video analysis. We have shown the differences in the performed tasks between the experts and the novices, and the reduction in time of embolization. The procedure, complications, and educational capabilities were evaluated ubiquitously positive. The confidence of the novices increased significantly after the training.

The simulator is intended to be the first practical experience for endovascular trainees in the transcatheter embolization with liquid embolic agents. The simulator shall serve as a teaching platform for learning procedural steps, handling embolic agents, familiarizing with the instruments, and highlighting possible complications. The educational validity of the simulators is a measurement of how reliant a simulator can convey knowledge and skills. In our study, we utilized the construct, face, and content validities. The construct validity identifies the level of expertise between the trainees [3]. Using video recordings and measuring the outcomes, we have observed differences between the experts and the novices. The experts occluded more chambers and made fewer mistakes (Fig. 4). We have observed significant differences between the experts and the novices in the duration of embolization, as well as the reduction of time required for occlusion (Fig. 5). The face and content validities are basic parameters demonstrating the simulator's representation of the trained tasks and its' teaching potential. [3]. In the surveys, the majority of the trainees evaluated our model and trained complications positively. The only negative opinion was regarding the authenticity of the catheter's gluing (Table 2). The simulator demonstrated a high educational value, based on the experts' surveys. The experts positively evaluated the teaching potential of the simulator and would incorporate our simulator into a hospital's residency program (Table 3). The self-reported change in the confidence level of the trainees is a measure of the subjective increase in their competence. We have observed significant improvements in the novice group on self-reported skill and knowledge level about every asked item ($p < .001$). The improvement in the management and understanding of the embolization demonstrates the training capability of the simulator. The smallest increase was observed in the confidence level of the independently performed procedure (Table 4). It is consistent with our intention to design the simulator intended to provide first experiences with embolization and not professional independence.

We believe simulation training should be an integral part of the IR residency. The proposed simulator would help inexperienced residents, provide a teaching platform for their first embolization experiences. Many institutions have already recognized the benefits of simulation-based training. The Cardiovascular

and Interventional Radiological Society of Europe (CIRSE) in its' current, second edition curricula from the year 2017, supports practice on simulators as a valid method of formal teaching and independent self-directed learning, contributing to growing professionalism [11]. The Royall College of Radiologists in the 2021 curriculum supports a simulation "as a useful tool to supplement training in clinical situations" [12]. Basic vascular intervention and angiography were mentioned as the essential procedures requiring simulation-based training in radiology [13].

We can divide endovascular simulators into animal, physical, and VR simulators [7]. They differ from each other on fidelity levels, reusability, ethical issues, purchase, and maintenance costs. In animal models, anesthetized animals undergo embolization procedures to train and evaluate, established, and new embolization techniques [14–16]. Those models provide excellent haptic feedback. Unfortunately, they impose many ethical and legal issues, are non-reusable, and offer a narrow range of possible simulations. They are problematic in transportation and storage. Preconditioned vascular pathologies, sedation of animals, monitoring of vital signs, and postoperative care generate additional costs [7, 17]. The physical simulators are devices typically replicating anatomical regions and are limited to the teaching of distinct technical procedures. They serve in the training of ultrasound-guided needle procedures, catheters' and guidewires' navigation, and stents' placement [18, 19]. The physical simulators are low-cost, easily transportable, and do not require an angiographic suite. The lack of multiple training scenarios and non-standardized evaluation are the disadvantages [7]. The VR simulators use computer models of human vasculature, that can be manipulated using simulated or actual medical devices. They offer standardized training scenarios, improving procedural skills i.e. vascular trauma management, uterine and prostatic artery embolization [4, 20]. Those simulators are reusable, provide feedback, measure procedure and fluoroscopy times. However, the high-end equipment, standardized to mimic clinical cases increases the production, purchase, and service costs of the VR simulators [7, 17].

The liquid embolization simulator seems to be the optimal choice for the simulation of the embolization with the liquid agents. Cost reduction, ease of implementation into clinical routine, small size, portability, and absence of ethical issues are the biggest advantages against animal and VR counterparts. The simplified anatomy, use of the real instruments, absence of costly liquid embolics (n-BCA, Onyx) and simulation of basic physiology (blood flow) create an adequate environment for the training of the embolization with the liquid agents, especially for inexperienced users.

Certain limitations can be attributed to our simulator and embolization training. Overall, we evaluated only a small group and we did not assess if the skills learned by our participants transfer to the procedures performed in the reality. To show a significant learning curve more training sessions with larger groups and follow-ups would be required.

In our opinion, our simulator enables effective embolization training in a friendly learning environment. The simulator provides the first hands-on experience of the embolization with the liquid agents. It offers inexpensive training opportunities for endovascular trainees and can serve as an additional element of the endovascular training.

Abbreviations

n-BCA: n-Butyl cyanoacrylate, IR: interventional radiology, VR: virtual reality, STL: stereolithography, SD: standard deviation, CIRSE: Cardiovascular and Interventional Radiological Society of Europe

Declarations

Ethics approval and consent to participate: All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Approval was obtained from the ethics committee of Charite Universitaetsmedizin Berlin. Informed consent was obtained from all individuals participants included in the study.

Consent for publication: Consent for publication was obtained for every individual person's data included in the study

Availability of data and materials: The datasets used and analysed during the current study are available from the corresponding author on reasonable request.

Competing interests: The authors declare that they have no conflict of interest.

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Author's contribution: MM established the methods, supervised the evaluation of the simulator and was major contributor in writing the manuscript. MS helped in the simulator's design and evaluation. MS M.D. recruited the experts, was the advisor and mentor of the research project and edited the manuscript. All authors read and approved the final manuscript.

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Tables

Table 1. Summarized answers of the participants to the questionnaire regarding the simulator (n = 17)

The model simulates the following tasks:	Strongly agree	Agree	Neither	Disagree	Strongly disagree
Navigation of the catheter and guidewire	8 (47)	9 (53)	0	0	0
Preparation of the embolic agent	9 (53)	7 (41)	1 (6)	0	0
Application of the embolic agent using the sandwich technique	11 (65)	5 (29)	1 (6)	0	0
Application of the contrast agent	10 (59)	7 (41)	0	0	0
Occlusion of the targeted vessel	6 (35)	11 (65)	0	0	0
The entire embolization procedure	5 (29)	9 (53)	3 (18)	0	0

Table 2. Summarized answers of the participants to the questionnaire regarding the complications (n = 17)

The model simulates the following complications:	Strongly agree	Agree	Neither	Disagree	Strongly disagree
Wrong vessel occlusion	10 (59)	6 (35)	1 (6)	0	0
Collateral vessel occlusion	11 (65)	6 (35)	0	0	0
Backflow of the embolic agent	12 (71)	5 (29)	0	0	0
Insufficient occlusion of the targeted vessel	8 (47)	9 (53)	0	0	0
Catheter's gluing	8 (47)	7 (41)	1 (6)	1 (6)	0
The identification and prevention of general complications	4 (24)	12 (71)	1 (6)	0	0

Table 3. Summarized answers of the experts to the questionnaire regarding educational validity (n = 5)

The model	Strongly agree	Agree	Neither	Disagree	Strongly disagree
Trains hand-eye coordination	4 (80)	1 (20)	0	0	0
Teaches procedural steps of embolization	4 (80)	1 (20)	0	0	0
Is well suited for the training of beginners in transcatheter embolization	2 (40)	3 (60)	0	0	0
Would be incorporated into a hospital's residency program	2 (40)	2 (40)	1 (20)	0	0

Table 4. Differences in self-reported assessment of the novices before and after the training (n=12)

Outcome	pre-training	post-training	P-value
Overall, I understand the embolization procedure with a liquid embolic agent	4,1	1,6	< .001
I know all the steps of the embolization procedure	4,5	2,1	< .001
I can reliably handle liquid embolization agent	4,8	2,5	< .001
I know the instruments needed for embolization procedures	4,3	2,0	< .001
I can independently perform embolization procedures	4,8	3,8	< .001
Total	4,5	2,4	< .001

Figures

Figure 1

Development stages of the simulator. a) The adapter (anteriorly) and the main body of the simulator (posteriorly) prepared to print in Preform b) The main body cured with ultra-violet light

Figure 2

Training environment composed of the simulator with the connected pump, LED panel, and portable camera

Figure 3

The simulator, LED panel and camera are hidden underneath the plastic box. The laptop, connected to the camera, displays the simulator.

Successfully performed tasks

Figure 4

Percentage of successfully performed tasks between the experts and the novices (n = 65)

The mean procedure times

Figure 5

The mean embolization times between the experts and the novices, including the SD (n = 65)