Title: Evaluation Method of Training Simulation on Biological Models for Cardiovascular Surgery Residents

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Running Title: Training Simulation for Cardiovascular Surgery

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CMAB - Design of study, critical analysis and revision

LRPD – Writing and acquisition of data

FJD – Writing and acquisition of data

RM - Critical analysis and revision

AIF - Critical analysis and revision

FBJ – Critical analysis and revision

Ethics Approval Statement

MEDICINA USP

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COMISSÃO DE ÉTICA NO USO DE ANIMAIS

Certificamos que o projeto intitulado "**Treinamento Prático do Programa de Residência Médica em Cirurgia Cardiovascular**", protocolo nº **062/16** sob a responsabilidade de **Fabio Biscegli Jatene** e **Carlos Manuel de Almeida Brandão**, apresentado pela Comissão Científica do InCor - que envolve a produção, manutenção e/ou utilização de animais pertencentes ao filo Chordata, subfilo Vertebrata (exceto o homem), para fins de pesquisa científica (ou ensino) - encontra-se de acordo com os preceitos da Lei nº 11.794, de 8 de outubro de 2008, do Decreto nº 6.899, de 15 de julho de 2009, e com as normas editadas pelo Conselho Nacional de Controle de Experimentação Animal (CONCEA), e foi aprovado pela COMISSAO DE ÉTICA NO USO DE ANIMAIS (CEUA) da Faculdade de Medicina da USP em reunião de 22.06.16.

Finalidade	(x) Ensino ( ) Pesquisa Científica
Vigência da autorização	Março/2017
Espécie/linhagem/raça	Peças porcino e bovino
Nº de animais	**Não se aplica**
Peso/Idade	Não se aplica
Sexo	Não se aplica
Origem	Frigorífico Rajá

CEUA-FMUSP, 22 de Junho de 2016

Dr. Eduardo Pompeu
Coordenador
Comissão de Ética no Uso de Animais

Waiver Statement

The present study do not include patients, so there is no Informed Consent.

Introduction

The great complexity of cardiac surgery carries along the challenge of training and the most resident physicians acquire technical skills in the operating room on real patients[1]. However, the exposure to cardiovascular surgery has decreased nationwide during general surgery and medical school, compromising the junior operative experience[2]. Thus, integrated 5-year cardiovascular residency program are currently a common stream for cardiac surgery training residents in Brazil and as they are accepted directly from medical school, have less surgical experience than traditional graduate of a general surgery training program[3].

It is also challenging for the institutions responsible for the training programs, since they are expected to offer an efficient and adequate curriculum, which relies on a paradox of providing safe surgical opportunity without compromising the postoperative outcomes and excellent patient care[4]. Operating room surgical training has significant limitations indeed, considering it provides short time to develop technical skills and has low tolerance for learning mistakes. In this context, we believe that incorporating simulation on biological models in our residency program could improve cardiac surgical training and patient safety, due to its potentiality to avoid surgical technical failure that would compromise the outcomes, bringing more safety, efficacy and better results in the longer term.

To achieve our goal of preparing residents to be able to play the right role in the operating theater and to develop their skills, in 2015 we started a weekly activity with their respective biological models which included the most

commonly performed cardiac surgical procedures. However, in order to make it more objective, better develop resident's surgical skills and enable a greater number of repetitions of the modules, in 2016 it was developed a program composed of the most elemental procedures in cardiovascular surgery, which included aortic valve replacement, mitral valve replacement and coronary artery bypass grafting (distal and proximal anastomosis).

Recognizing these challenges about technical skills acquisition for cardiovascular surgery, we evaluated our simulation training program on biological models for the medical residency of cardiovascular surgery at our institution.

Materials and Methods

The simulation training program on biological models for the medical residency of cardiovascular surgery at our institution was approved by the ethics committee of University of Sao Paulo Medical School.

It was established one wet lab session weekly lasting 2 hours, coached by an expert cardiovascular surgeon and by the chief of residents at the department of experimental surgery at our institution. Second and third-year cardiovascular surgery residents were selected for this simulation training program.

The biological models chosen for simulations were porcine and bovine hearts obtained from slaughterhouses. Bovine heart was used for coronary artery bypass grafting surgeries and aortic valve replacements training and porcine hearts for mitral valve replacement simulation. During coronary artery bypass grafting simulation, chicken trachea was used as an arterial graft, since its thickness and wall structure is little more consistent than a mammary or radial artery. Valve prostheses received as donation were used in valve replacement simulations. These simulator boxes bring a more realistic scenario of the operation, once the hearts are placed at the anatomic perspective and therefore in a deeper position, like in real life. They are made of synthetic material that is lightweight, easy to carry on, to clean and lifelong lasting (**Figure 1**)[5].

For the purpose to optimize resident's performance, we predetermine that there should have no more than two residents for each heart, and it was imperative that both of them perform the whole procedure as the main

surgeon at least once. Each resident repeated the sessions five times during the course of the program. The modules were selected to allow better practical performance and evaluate the improvement of resident's surgical skills.

In order to evaluate our simulation program in biological models, at the end of training program an objective and a subjective evaluation were applied. For objective assessment, each resident was submitted to a practical test of 2 modules that were carried out during the semester. The chosen sessions for the practical test were a valve replacement and the distal anastomosis of CABG. For each module, items that addressed performance on specific abilities were assessed using a 5-point scale.

For valve replacement module five objective items were rated using a 5-point scale, which were the valve excision skill, precision of anatomical structures identification, the valve annulus stitches quality, proper prosthesis positioning and the time of execution of the task **(Figure 2)**. Regarding to CABG module, five objective items were rated using a 5-point scale also. The tasks evaluated were the anterior descending artery identification, coronary arteriotomy skill, graft tailoring and anastomosis performance, anastomosis quality and time of execution of the module (**Figure 3**).

To provide a subjective assessment, each resident filled out a questionnaire consisting of 3 items reviewing the overall quality of the workshops, rated by a 10-point scale. The subjective items were addressed to the expert's didactics, the simulation performance quality and the simulator fidelity.

Results

The repetition of modules and the gradual increase in complexity showed clear relationship with technical skill development. Both suturing dexterity and surgical planning had a notable improvement. Also, it was remarkable the resident's ability enhancement to assist his or her teammate while acting as first assistant, helping to create a better surgical field exposition.

In the objective evaluation applied at the end of the training program, consisted by valve replacement and CABG modules, most of residents received high scores in all the practical tasks evaluated. The mean performance rating scores of components of valve replacement module on a 5-point scale ranged from 4.2 to 4.79 (**Table 1**). For coronary artery bypass grafting, the mean performance rating score of tasks on a 5-point scale ranged from 4.33 to 4.87 (**Table 2**).

In the subjective assessment, all items evaluated, such as expert's didactics, simulation performance and biological simulator fidelity, received high grades (**Table 3**).

In addition, all of residents reported an excellent simulator fidelity allowed by the simulator box used to place the hearts into. Interestingly, familiarity and comfort in the operating room was felt to be improved for both residents and faculty. This perception was emphasized at the end of questionnaire, being described as its highlight. The participants reported that they felt much better prepared to perform each skill in the operating room.

Moreover, the simulation environment was perceived as more appropriate for technical skills training compared with clinical setting.

Discussion

The present report describes our experience in developing a simulation training program with biological models and its implementation in our cardiac surgery residency curriculum. Several studies have validated the need for simulation in cardiac surgery[6-8] and with the recent integrated 5-year cardiac surgery residency program emerged the necessity of curriculum restructuring to incorporate simulation into the residency training, since the new program implicates in less-experienced learners with decreased technical skills compared with the traditional graduate of 2-year general surgery as pre-requisite.

In addition, concerns have been raised about the safety of training surgeons in the performance of cardiac surgery. In fact, there is growing demand for improved clinical results and excellent outcomes, with intense public scrutiny of their clinical performance[9]. That's why surgical training in this field requires balance between standard of care delivered to patients and provision of sufficient operative exposure to trainees who are the cardiac surgeons of the future[10].

The combination of patient safety concerns, changes in resident education and more complex procedures in high-risk patients have generated greater interest in simulation-based learning in cardiac surgical training[11]. Considering the current educational environment and the importance of training the next generation of surgeons, simulations seems an attractive alternative. We strongly believe that simulation may contribute to the

development of technical skills and procedural knowledge required for adequate performance in the operating room.

Stephens et al.[12] reported that the frequency of simulation by residents of cardiothoracic surgery in United States has increased from 1%, in 2010, to 24%, in 2012. Certainly, surgical simulation allows the medical resident to perform in a less stress environment and may provide structured graduated training for technical abilities. Furthermore, educators recognize this activity as one method by which expertise may be developed and assessed[13].

Burkhart et al.[14] studied the high-fidelity Orpheus Cardiopulmonary Bypass Simulation System (ULCO Technologies, Marrickville, Australia) as an educational tool and observed significant improvement in confidence and knowledge, and participants preferred this simulation training over classroom and clinical-based learning.

Fann et al.[15] reported improvement in coronary anastomosis with cardiac surgery trainees using portable task station and on a beating-heart model. In general, average time to fully perform the anastomosis on the task station and on a beating heart decreased 20% and 15%, respectively.

Regarding the simulation models for surgery training, despite high fidelity, human corpse training has being discouraged, for two main reasons. First not always are there available corpses for use in good preservation conditions. Second is the short period of time that is speared for the training, since those patients have to be hand out the families for the ceremonial. Animal models to gain proficiency in surgical skills allow accurate simulation, however the costs are substantial and has important legal and ethical

implications[16]. Biological models, compared to animal models *in vivo*, have the advantage of lower cost and storage capacity for days in the refrigerator. In addition, they enable a realistic tissue feel and excellent anatomical correspondence. We observed that biological models with porcine or bovine hearts provided a high degree of realism and in the case of cardiac surgery, where surgical failure may result in patient morbidity and mortality, such a realistic simulation could reproduce better surgical results, which is essential before clinical application. In addition, biological models are low cost effective high-fidelity tool, which is very desirable considering the current financial constraints of most residency training programs.

The Brazilian Society of Cardiovascular surgery develops a "Hands On" training course performed at the National Congress[5] since 2009, with great acceptance among surgeons and residents, which included the most commonly performed cardiac surgical procedures. In our "Hands on Program", explanted porcine or bovine heart model placed within the plastic container replicates the confined mediastinum space in which heart surgery is performed, with all residents confirming its realistic exposure. In the simulators used in our sessions, the heart is anatomically positioned to expose the structure that will be approached on the intervention, mimicking a normal surgical field and offering the same level of difficulty of an intervention on a patient[5]. Therefore, this simulator provided a model to practice the majority of cardiovascular surgeries performed in our institution.

Another positive aspect of simulation-based skills training in cardiovascular surgery has been the notion that educators can spend more time teaching in a less stressful environment, what we confirmed during the

sessions[17]. Also, Fann et al.[18] demonstrated that teaching behaviors differ in the simulation compared with the operating room, particularly in the components of better focus, communication of goals and promoting understanding and retention.

In a similar way as described by Feins et al.[19], an assessment tool that addressed performance on specific skills was applied at the end of training program. Since technical competence is such a critical element of outcome in cardiothoracic surgery, many believe consideration should be given to an objective assessment of technical skills and should be included in the certifying process for this surgical specialty[20,21].

In addition, the resident responses in the subjective analysis revealed high satisfaction with the training program. They highlighted as positive aspects the realistic tissue feel and anatomical representation, as well as the possibility to perform a specific technique multiple times thereby improving skill acquisition. In general, most believed that the program provided a realistic experience and was valuable in teaching surgical skills.

Whether improved performance in the simulation laboratory is transferable to the operating room is not easily addressed, but most trainees reported that they felt much better prepared and less anxious to perform each skill in the operating room environment. These findings support those found in the published literature that providing structured teaching sessions improves the confidence level of the learners[22].

The actual integrated 5-year residency program, with younger and less experienced students demands incorporation of simulation-based training modules at the cardiac surgery educational curriculum. For simulation-based

learning to be successful and well fully adopted, institutional commitment with resources and available educational time is crucial. The cost of simulation-based learning, both in equipment and faculty time, must be recognized at the institutional and national levels so that initial and ongoing funds are available[23]. They must know that training competent and technically proficient surgical residents is critical to the future of cardiovascular surgery.

We hope the description of our experience provide valuable information for redesign residency curriculum of the future cardiac surgeons. It is necessary that the institution became the main sponsor of this initiative, providing regular and adequate space and material for the training process, with dedicated senior surgeons to teach residents their skills.

Conclusions

Simulation training on biological models for cardiovascular surgery residents is an effective method of learning surgical skills in cardiovascular surgery.

Figures

Figure 1- Simulator boxes used in training (GBS Simuladores Médicos LTDA®)

A – Simulator for CABG procedures

B – Simulator for Valve Replacement procedures

Figure 2- Training simulation - CABG procedure training

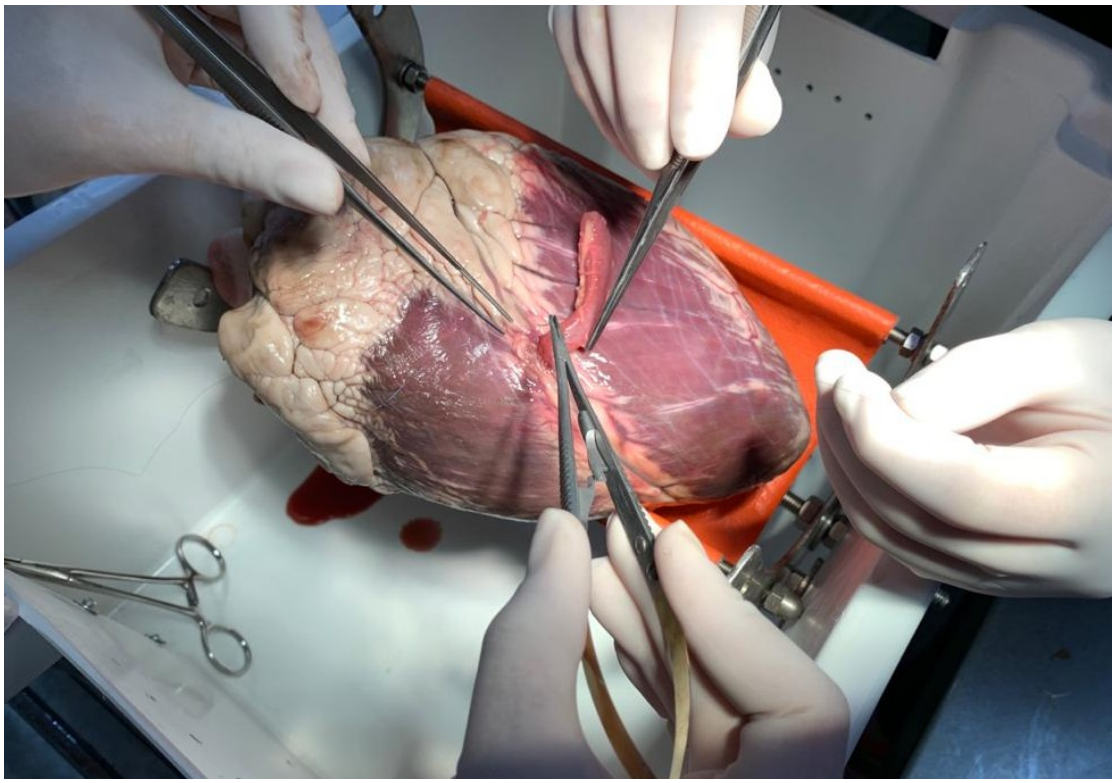
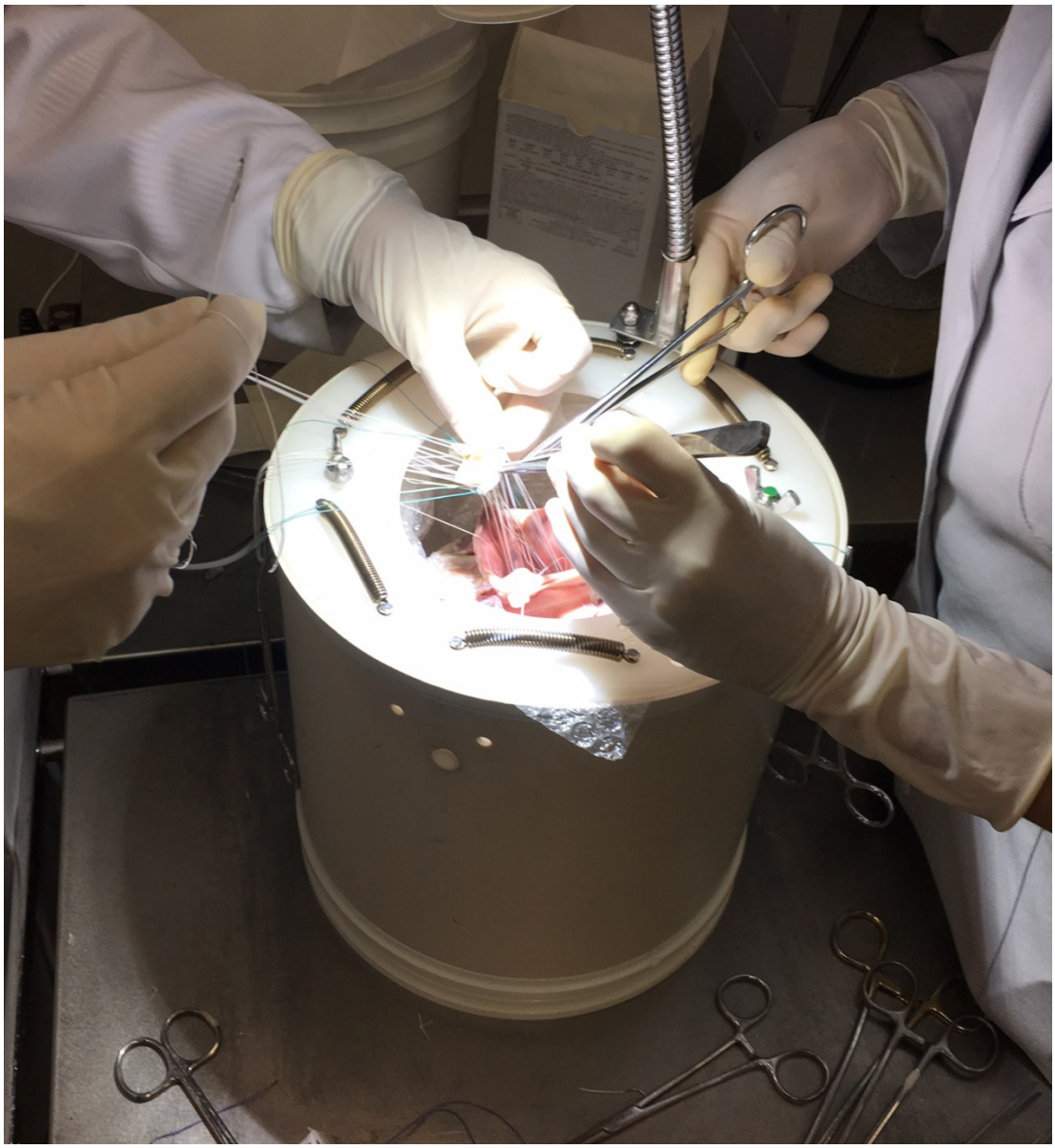


Figure 3- Training simulation - Aortic Valve Replacement procedure training



Tables

Table 1: Objective performance evaluation: aortic and mitral valve replacement procedures, using a 5-point scale.

Task	Residents (N)	Lowest Grade	Higher Grade	Mean score
Anatomy knowledge	16	4	5	**4.79**
Valve excision	16	3.5	5	**4.72**
Stitches in valve annulus	16	3.5	5	**4.47**
Prosthesis implantation	16	3	5	**4.34**
Time	16	3	4.5	**4.2**

Table 2: Objective performance evaluation: coronary artery bypass grafting procedure, using a 5-point scale.

Task	Residents (N)	Lowest Grade	Higher Grade	Mean score
Anterior descending artery identification	14	4	5	**4.87**
Arteriotomy	14	3.5	4.5	**4.33**
Graft handling	14	3.5	5	**4.42**
Proximal anastomosis quality	14	3.8	5	**4.75**
Distal anastomosis quality	14	3.5	5	**4.6**
Time	14	4	4.5	**4.55**

Table 3: Subjective performance evaluation, using a 10-point scale.

Sessions	Residents (N)	Expert's didactics (*)	Simulation performance (*)	Simulator fidelity (*)
Mitral valve replacement	**16**	**9.9**	**9.5**	**9.2**
Aortic valve replacement	**16**	**9.9**	**9.6**	**9.2**
CABG (Proximal anastomosis)	**14**	**9.78**	**9.42**	**9.0**
CABD (Distal anastomosis)	**14**	**9.8**	**9.7**	**9.4**

**Data are expressed as means.*

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