PROVESA trial

Proficiency based progression training for robotic vesico-urethral anastomosis chicken model versus the Halsted's model: a cross-specialty, multicentric, randomized and blinded clinical trial.

Study Protocol

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Summary

In a prospective, randomized and blinded study robotic naïve (urology (n = 12), surgery (n = 12) and gynecology (n = 12)) residents (*n* = 36) from the KU Leuven and University of Gent residency training programs will be randomized (in equal discipline numbers) to Traditional Halstedian apprenticeship type training or proficiency based progression (PBP) training to learn to perform a vesico-urethral anastomosis (VUA) on a chicken model. Both groups will receive the same e-learning (on how to perform the VUA on the chicken model) and skills laboratory robotic training curriculum. The PBP trained group will however be required to demonstrate quantitively defined proficiency benchmarks for training progression (i.e., from e-learning to the skills lab). The PBP group will also have a defined benchmark to demonstrate before training is deemed completed. The Traditional trained group will train in the same skills laboratory for a case-matched period of time as the PBP group, with the same level of supervising faculty proctors and using the same training resources but with no proficiency benchmarks or metric-based feedback. Both groups will be required to perform a VUA on the chicken model before skills training proper and at the end of training. Investigators will be trained in pairs to assess VUA performance from a pre-defined set of explicitly defined binary metric events reliably (inter-rater reliability > 0.8). They will also be blinded as to the identity of the trainee performing the procedure, how they were trained (i.e., group) and procedure order.

H_1 It is hypothesisied that iimplementation of PBP training in teaching the robotic suturing of VUA leads to better surgical training outcomes (i.e., lower number of performance errors) when compared to Halsted's method.

Proficiency based progression training for robotic vesico-urethral anastomosis chicken model versus the Halsted's model: a prospective, randomized and blinded clinical trial.

Introduction

Current surgical training is outdated.[1] The Halsted's model 'See one, Do one, Teach one', is still widely used during training of surgeons. Consequently, a patient is still exposed to a novice resident who does the procedure for the very first time. For too long, surgical training is dependent on the quality of the trainer with a lack of systematics, standardization and objective scoring systems.[2] Because of financial and ethical reasons, it can no longer be justified that the beginning of a learning curve takes place in the operating room on real life patients. By mitigating the initial learning curve in an out-of-hospital setting and by developing a standardized, novel training system, patient safety could be improved.

Proficiency Based Progression (PBP)[3-5] training or Quality Assured Training is a novel training method that already has demonstrated its value in different surgical specialties.[6-12] In this kind of training a specific level of performance defined by a quantitative score (benchmark) or scores on a standardized assessment must be demonstrated to gain the proficiency level. Only demonstrating the ability to meet quantitatively defined performance benchmarks permits progression in training (i.e., proficiency-based progression [PBP] training).

Background

Suturing and knot tying are fundamental skills for all surgical disciplines. They serve an important clinical function but using a minimally invasive approach means that they are even more challenging to complete. A curricular approach to learning laparoscopic suturing and knot tying has been successfully demonstrated for Nissen fundoplication.[10]

Fundamental in creating a proficient robotic surgeon is the acquisition of basic surgical skills, such as suturing and knot tying.[13] Some training models mimic the real anatomical environment in which a procedure will be performed and provide trainees with the opportunity to learn and practice their skills before starting their practice on real cases in the operating room. Numerous dry-lab, wet-lab, and virtual reality simulation models have been described.[14] The "Venezuelan chicken model" is generally accepted as a optimal model for trainees to learn robotic suturing, anastomosis and knot tying tasks (for all surgical disciplines).[14-16] We will use the Venezuelan chicken model in this study. It has several advantages; it is inexpensive, widely available, easy to prepare, it is a good model for the urethro-vesical anastomosis training, it is possible to introduce a catheter and performing the leakage test, it takes the trainee approx. 20 mins to complete the task. Over the past 12 months ORSI has developed and validated (Delphi consensus and Construct Validity) performance metrics for the task.

This study aims to compare the effectiveness of Halsted's apprenticeship approach to training with the Proficiency Based Progression (PBP) approach for teaching the robotic suturing of a vesico-urethral anastomosis (VUA) on a chicken model.

Methods

Subjects

Robotic naïve urology (n = 12), surgery (n = 12) and gynecology (n = 12) residents (*n* = 36) from the UKU Leuven and University of Gent residency training programs will participate. They will be randomized (using an online randomizer https://www.random.org/) to teaching of VUA suturing with either Halsted's (*n* = 18) or the PBP method including procedure-specific, validated metrics (*n* = 18).

Procedure and training

Trainees in the Traditional trained group will be trained according to the traditional approach of 'See one, do one, teach one' principle. Trainees will have a e-learning didactic component (specifically on the anatomy & physiology of the procedure, clinical aspects of the procedure, published evidence etc) which they must complete before training by a procedure expert. On completion of the e-learning module they will complete a summative assessment of their knowledge. They will then be shown how and then trained to suture and tie knots using the robot. The VUA will be demonstrated initially by an expert and who will then proctor the trainees in the same technique for repeated training trials., i.e., repeated practice for a period of time matched to the PBP group.

Students in the PBP trained group will follow the exact same e-learning didactic course as the Traditional trained group but the PBP group will be required to pass a test of procedure knowledge before continuing to the surgical training. Their knowledge will be assessed in a formative and summative fashion. After their initial VUA assessment, procedure-specific and validated procedure metrics will be used to teach the students the steps of the procedure, as well as the correct (and incorrect) way to perform the procedure. The metrics will be used to give them performance feedback with specific advice on how they might improve their performance, i.e., deliberate practice.[17]

Both groups of subjects will receive the exact same amount of training and have access the same didactic and training resources. Both groups will also complete a baseline assessment on the chicken model before technical skills training. Assessors, blinded to group membership and procedure order (first or last procedure) will evaluate each student's first and final VUA with the validated chicken anastomosis metrics. They will also assess performance with the GEARS[18] assessment tool (Figure 2). Additionally, the student's satisfaction of the training method will be assessed using a Likert scale 1-5 (Figure 3).

Proficiency Definition: In the study proposed here proficiency levels will be quantified and defined on the objectively assessed performance of surgeons experienced in performing that VUA task being trained. This performance level will be established from the construct validation study of the procedure metrics derived from the procedure characterizations.[4, 5, 19]

Performance assessments

Investigators will be trained in pairs to assess performance from a pre-defined set of explicitly defined metric events reliably (inter-rater reliability > 0.8). They will be blinded as to the identity of the trainee performing the procedure, how they were trained (i.e., group) and procedure order.

Procedure performance assessment

We will record how long subjects took to perform the procedure, the number of steps correctly completed and procedure errors/deviations from optimal performance. We will also record and cost the instrumentation/needles/suture etc utilised in the performance of the procedure.

Baseline Assessment: -Prior to the commencement of education and training protocol all subjects from both groups will be assessed on their performance of the VUA task. Performance on the procedure will be video recorded and assessed as previously described.

Statistical Analysis: From previous similar studies, it has been found that data has been reasonably normally distributed and suitable for parametric statistical analysis. If the data violates any of the assumptions of normality, data will be compared for statistical significance with Mann-Whitney U for comparison between two independent samples and Wilcoxon signed-rank test. Where data are normally distributed with approximately equal variance differences between groups, task performance will be compared for statistical significance with two-factor Analysis of Variance where factor one is the type of training subjects received and factor two is the order the task was performed (i.e, baseline performance and end of training performance). The same analysis will be used to assess the binary checklist metric scores and the GEARS scores (seperatly) for the Standard trained and the PBP trained groups. Specific post hoc statistical contrasts between surgeon groups performance within a training condition (i.e., between the objectively assessed performance of urology, surgery and gynecology residents) will be done with Scheffe F-tests.

Statistical power calculation: A pilot study has shown that novices on average make 16.6 (SD = 4) performance errors on the task. Assuming a reduction of ~40% with PBP training (i.e., 16.6 vs 10 errors) with a standard deviation of n = 4, an Alpha – 1% with 16 subjects in each group would yield a statistical power of 0.998 for the proposed study.

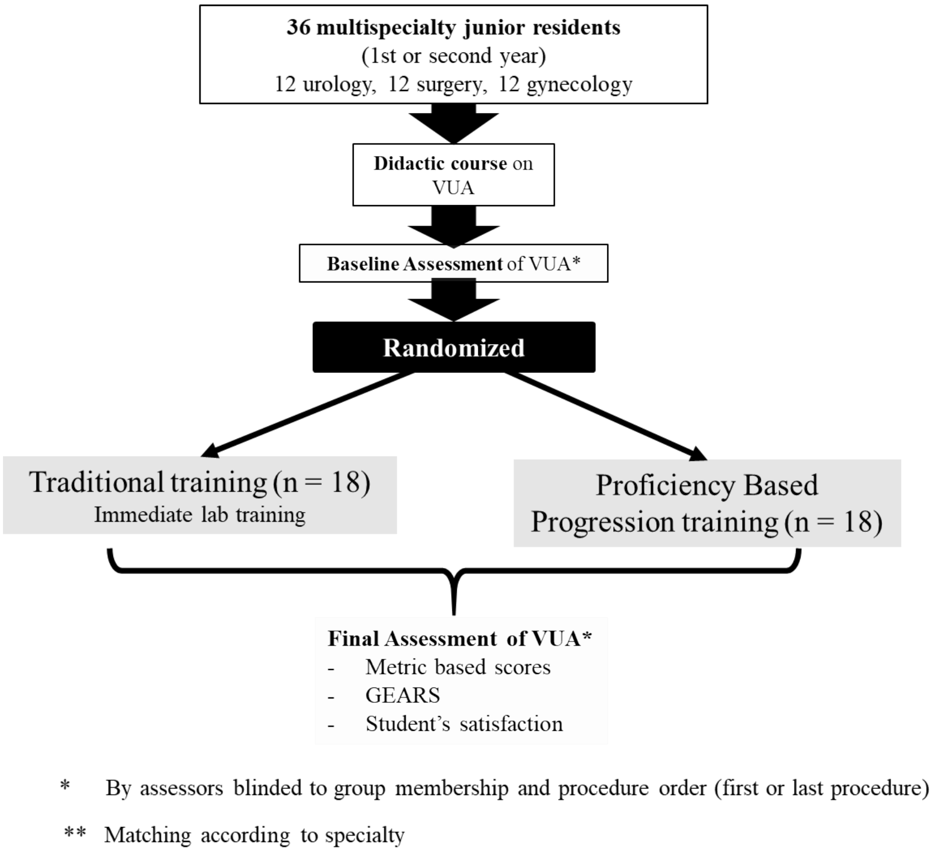

Figure 1. the design of the prospective randomized study to evaluate the impact of PBP on learning the robotic surgical skills for a vesico-urethral anastomis (VUA) on a chicken model.

Hypothesis

H_1 Implementation of PBP training in teaching the robotic suturing of VUA leads to better surgical training outcomes (i.e., lower number of performance errors) when compared to Halsted's method.

H_0 There will be no difference in the procedure knowledge prior to VUA training

H_0 There will be <u>no</u> difference in the objectively assessed procedure performance of the urology, surgery and gynecology residents at the end of training in the PBP group

H_0 There <u>will</u> be a difference in the objectively assessed procedure performance of the urology, surgery and gynecology residents at the end of training in the Traditional trained groups.

H_0 There will be no difference in student satisfaction with the two approaches to training.

Depth perception

1	2	3	4	5
Constantly overshoots target, wide swings, slow to correct		Some overshooting or missing of target, but quick to correct		Accurately directs instruments in the correct plane to target

Bimanual dexterity

1	2	3	4	5
Uses only one hand, ignores nondominant hand, poor coordination		Uses both hands, but does not optimize interaction between hands		Expertly uses both hands in a complementary way to provide best exposure

Efficiency

1	2	3	4	5
Inefficient efforts; many uncertain movements; constantly changing focus or persisting without progress		Slow, but planned movements are reasonably organized		Confident, efficient and safe conduct, maintains focus on task, fluid progression

Force sensitivity

1	2	3	4	5
Rough moves, tears tissue, injures nearby structures, poor control, frequent suture breakage		Handles tissues reasonably well, minor trauma to adjacent tissue, rare suture breakage		Applies appropriate tension, negligible injury to adjacent structures, no suture breakage

Autonomy

1	2	3	4	5
Unable to complete entire task, even with verbal guidance		Able to complete task safely with moderate guidance		Able to complete task independently without prompting

Robotic control

1	2	3	4	5
Consistently does not optimize view, hand position, or repeated collisions even with guidance		View is sometimes not optimal. Occasionally needs to relocate arms. Occasional collisions and obstruction of assistant.		Controls camera and hand position optimally and independently. Minimal collisions or obstruction of assistant

Figures 2. The GEARS assessment tool

TRAINING EVALUATION FORM

Course name:______________________________

Instructor: _________________________ *(Please fill out one for each instructor)*

Date: ______________

Training Quality					
The overall quality of the training I received was high	*Strongly Disagree*	*Disagree*	*Neutral*	*Agree*	*Strongly Agree*
This training will be beneficial to me in the performance of my job	*Strongly Disagree*	*Disagree*	*Neutral*	*Agree*	*Strongly Agree*
Course Presentation					
The methods of content delivery (lectures, PowerPoints, etc.) were appropriate for this course.	*Strongly Disagree*	*Disagree*	*Neutral*	*Agree*	*Strongly Agree*
The course material was easy to understand and helpful.	*Strongly Disagree*	*Disagree*	*Neutral*	*Agree*	*Strongly Agree*
The topics were presented in a logical order.	*Strongly Disagree*	*Disagree*	*Neutral*	*Agree*	*Strongly Agree*
The vocabulary used in the course was clear and easy to understand.	*Strongly Disagree*	*Disagree*	*Neutral*	*Agree*	*Strongly Agree*
The instructor was knowledgeable and effective.	*Strongly Disagree*	*Disagree*	*Neutral*	*Agree*	*Strongly Agree*
Course Objectives					
The course covered the material I expected.	*Strongly Disagree*	*Disagree*	*Neutral*	*Agree*	*Strongly Agree*
The times scheduled for the agenda items were appropriate.	*Strongly Disagree*	*Disagree*	*Neutral*	*Agree*	*Strongly Agree*
The course met the training objectives.	*Strongly Disagree*	*Disagree*	*Neutral*	*Agree*	*Strongly Agree*
The course met my training needs.	*Strongly Disagree*	*Disagree*	*Neutral*	*Agree*	*Strongly Agree*

Figure 3: Likert-scale for the assessment of training satisfaction

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