Validation of a Training Model for Performing Laparoscopic Knots and Stitches in a Simulation Environment

Validação de Modelo de Treinamento para Realização de Nós e Pontos Laparoscópicos em Ambiente de Simulação

ABSTRACT

Introduction: To evaluate the progression of competence, learning curve and degree of satisfaction with the training model of medical students undergoing training to perform laparoscopic knots in a simulator.

Methods: This was a prospective, longitudinal, interventional study, carried out from April 2016 to July 2017, with the participation of 52 students from the Centro Universitário Christus, Fortaleza, Brazil, from the first to the third year of medical school, undergoing theoretical practical, systematic, and methodized training, with progression of skills to perform laparoscopic knots in a simulation environment in four stages, with a total duration of 16 hours. It was established the task of performing laparoscopic stitches, with five simple knots, in the beginning and in the end, in a suture mold, in an abdominal cavity simulator, in 18 minutes. The main outcomes were time and quality of performance. The students were evaluated before the first and after all stages of the training regarding the quantity and quality of the knots or the subject of the stage and satisfaction with the training model. ANOVA and Student’s t tests were performed for the independent samples and the chi-square test for the categorical variables. For variables with serial measurements, general linear models were used. Univariate binomial models were used in the evaluation variables of the training model. P values <0.05 were considered significant.

Results: The values of the medians were analyzed between the first and last stages of the training; of the number of simple knots (0.0 and 15.0) and laparoscopic knots (0.0 and 3.0), the adequacy of the sizes of the suture tail ends (0.0 and 11.0), the number of adjusted initial simple knots (0.0 and 3.0) and adjusted sequential ones (0.0 and 24.0). There was statistical significance in all evaluated parameters (p< 0.001). The learning curve showed that 99.1% of the students attained competence. The degree of satisfactory evaluation of the training model was considered good or great in 97% or more, with statistical relevance in 8 of the 10 evaluated statements.

Conclusions: The study demonstrated that the students showed competence progression and learning curve evolution. The degree of student satisfaction in relation to the training model stages was very significant.
INTRODUCTION

The current model used for the training of surgeons was proposed and implemented by William Halsted, at John Hopkins Hospital, in 1889, in the United States. The initial model introduced the concept of medical residency based on the German experience of training for surgeons. Over time, this training model was gradually adopted in the United States and throughout America. Classically, this training is carried out in the operating room under the supervision of a graduated surgeon. This type of training was based on the German experience of training for surgeons. Over time, it became clear that the training model proposed by Halsted (‘see one, do one, teach one’) would not apply to learning the minimally-invasive surgery skills and would have to be replaced by one that prioritized simulation with many repetitions, always under qualified supervision.

Aiming to facilitate the training of new psychomotor skills, simulators and simulation environments were developed, thus eliminating the risks of iatrogenesis in the immediate training and offering trainees a safe, comfortable environment, free from the pressure of the operating room.

With the natural evolution of video-assisted surgery, abdominal procedures became increasingly more complex and little by little, it became necessary to perform intracorporeal knots, stitches and sutures. At the initial procedures, it became evident that these maneuvers were difficult to perform, and they started to be considered highly complex procedures. To overcome this difficulty, some training models for performing knots, stitches and intracorporeal sutures in laparoscopic surgeries have been proposed and applied. Nevertheless, the great difficulty in providing surgeons with effective laparoscopic learning persists.

The Society of American Gastrointestinal and Endoscopic Surgeons, endorsed by the American College of Surgeons (ACS), proposed in 2004, an educational training program called ‘Fundamentals of Laparoscopic Surgery’ (FLS) with the aim of teaching and evaluating the basic psychomotor skills required in the performance of laparoscopic surgery for residents and surgeons. The training is based on the repetition of

of laparoscopic intracorporeal knots, requiring specific training in minimally-invasive surgery.

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the proposed tasks. The European Society of Endoscopic Surgery has implemented a training program for surgeons and residents called Laparoscopic Surgical Skills (LSS). The structure of this program consists of three phases and all of them include theoretical and practical activities.

Sadideen et al. (2012) suggested that, to facilitate the learning of psychomotor skills in mini-invasive surgery, aspects of educational theories should be incorporated into the training.

The concepts of Dave’s Taxonomy, established in 1967, guide the acquisition of psychomotor skills. Fitts and Posner’s theory establishes that learning occurs through the acquisition and retention of psychomotor ability, in three sequential stages: cognition, association and autonomy; Erikson’s theory aims at developing the skill after repeated practice of the exercise. Miller’s theory proposes a hierarchical sequence of competence on four levels, based on “knowing”; followed by “knowing how”, “demonstrating how” and, finally, “doing” and thus, established the step-by-step for competence, in which the trainee develops by going through the cognitive and behavioral steps necessary for the next phases.

Recognizing the difficulty in acquiring the skills in performing laparoscopic knots and stitches, a training model was proposed with the incorporation of taxonomy with educational objectives and aspects of learning theories to assess the progression of competence, the learning curve and the degree of satisfaction of medical students.

METHODS

Study design

This is a prospective, longitudinal and interventionist study, of the pre- and post-type, aimed at assessing the progression of competence, learning curve and degree of satisfaction of medical students submitted to a model of theoretical and practical training in the performance of laparoscopic knots in a simulation laboratory. The assessment of medical students not yet in contact with surgical procedures aimed at the evaluation of individuals with close to no experience in the technique then evaluated.

Study site and sample

To calculate the sample size, an 85% adequacy rate was considered at the end of the training, with a maximum error of 5 percentage points and a 95% significance level, resulting in 49 students. Then, 52 medical students from the first to the third years from Centro Universitário Christus, Fortaleza, Ceará, were admitted to the research protocol from April 2016 to July 2017. The students were of both genders, older than 18 years and did not have any anatomical and/or functional limitations for the performance of the proposed tasks. All of them were volunteers. The study was carried out in the surgical skills laboratory, in four shifts, totaling 16 hours of training/qualification. A maximum of eight participants were accepted for each training session.

Training model

The training model for performing surgical laparoscopic knots and stitches consisted of theoretical and practical teaching/learning activities, divided into four stages. Each stage, in turn, was subdivided into two training stations. The stages lasted approximately four hours, which corresponded to a training shift, and were standardized and carried out as follows: all stages started with the presentation of the objectives, theoretical aspects and evaluation models used in the training. Then, the materials, instruments, equipment and how to perform the proposed maneuvers were demonstrated. This was followed by the demonstration of the maneuvers by the teacher, in the usual time and velocity and then in stages, step by step, as many times as necessary until full understanding by the students. Soon after that, they were encouraged to perform the cognitive domain of the proposed skill steps and then to perform and repeat them until complete mastery of the skills was attained, that is, their performance without errors. Throughout the training process, the students were supervised by a teacher or instructor, who were always the same, at the proportion of one (teacher/instructor) for two (students). Dave’s Taxonomy and Miller’s, Ericsson’s, Fitts and Posner’s, Boud’s, Schon and Ende’s (feedback) theories were used as the basis of practical theoretical training.

Each stage of the training model had a specific objective and were distributed in progressive degrees of difficulty to facilitate training in performing surgical knots, stitches and sutures in a laparoscopic environment. The first stage aimed at training to develop skills in performing knots and manual stitches. The second stage designed the training to develop skills in performing instrumental surgical knots, stitches and sutures. The third step was based on adapting to the simulated environment of laparoscopic surgery and training to develop skills in performing knots, stitches and sutures with direct vision (three spatial dimensions), through the laparoscopic window of the laparoscopic surgery simulator. The fourth stage had the same objectives as the third stage and differed in that it was performed with indirect vision (two spatial dimensions) through the video monitor of the laparoscopic surgery simulator (Figure 1).

![Figure 1](image-url)

Source: Author.
The evaluations took place at the beginning of the first stage and at the end of the others. At the end of each stage, students were evaluated by performing the procedures for which they had been instructed at that specific stage and, before the first stage, the laparoscopic stitches. The laparoscopic stitches were evaluated regarding both quantitative and qualitative aspects. For the quantitative evaluation, the number of half-knots and laparoscopic stitches performed, or the correction of the station technique were measured.

The qualitative evaluation considered: following the previous marking of the stitches, the size of the suture tail ends, the adjustment of the initial half-knot and the adjustment of the sequential half-knots to the initial one of the surgical stitches. All students were evaluated simultaneously, with the evaluation lasting 18 minutes. To perform the test, the students had a laparoscopic environment simulator (EndoSuture Training Box®), a needle holder, a grasping forceps and scissors, all for laparoscopic use, in addition to a 22-cm long silk suture thread, with a 2.5-cm cylindrical needle and a synthetic suture plate made of thermoplastic elastomer in the shape of a human stomach with grooves to perform the knots and surgical stitches (Figure 2).

Variables

The students’ demographic data were collected at the time of enrollment for training. The following data were evaluated: age, gender, dominant hand, ability to type on cell phones and computer keyboards, previous experience in conventional and laparoscopic surgery, practice of musical instruments, video games and the desire to exercise surgical activities in the future.

To assess the progression of competence in performing laparoscopic knots and stitches, students were instructed to perform the highest number of laparoscopic stitches, each one adjusted with five half-knots, on a synthetic suture plate using a 2.0 silk suture thread, a 2.5-cm cylindrical needle with 3/8 of curvature, respecting the previous markings on the suture mold, without leaving any space between the initial and sequential half-knots and with the suture tail ends being sectioned between 5 and 7 mm within the determined time of 18 minutes. At the end of the evaluations, the suture molds were removed from the internal component of the simulator and then measurements and photographs were taken. The results of each student at each stage of the research were discussed individually and supervision was given on how to improve their performance (feedback). At that time, students were encouraged to reflect on their performance and strategies for improvement were defined.

A satisfaction survey was carried out with the research participants, through the psychometric response, Likert Scale, with a qualitative-quantitative, objective-subjective questionnaire, to measure the level of agreement, or not, to each statement related to the training model, material and environmental conditions and correlations between the stages of training. The answers were standardized and had a corresponding numerical score as shown below: I don’t totally agree (1), I don't partially agree (2), indifferent (3), I partially agree (4) and I totally agree (5). The applied questionnaire proposed to determine the adequacy of each stage of the training model to the objectives proposed by the pedagogical structure and consisted of ten statements. The stages of the training model were separately evaluated by the 52 students. At the end, the results of the evaluations of all stages were grouped in a table with total numbers and percentages of answers according to the established scores, as well as the level of significance of the answers with more than 90% in the items I partially agree, and I totally agree.

Statistical analysis

Initially, the standard descriptive statistical analysis was performed, such as calculations, central tendency measures (mean, standard error of mean and median) and distribution of absolute and relative frequencies. The results were expressed using tables and graphs. For the comparison of data from independent samples, parametric tests (ANOVA) were used. In the case of variables with a non-normal distribution, non-parametric tests (Mann-Whitney and Kruskal-Wallis) were used. The chi-square test was used for categorical variables. For variables with serial measures, the general linear model, ANOVA of repeated measures, with adjustment of the variables to normality, univariate and multivariate analyses were used. In the case of multivariate analysis, the model was adjusted for covariance analysis. Univariate binomial models were used to verify the percentage

Figure 2

(A) Surgical skills laboratory at Centro Universitário Christus. (B) EndoSuture Training Box® simulator and instruments. (C) Synthetic suture plate in the shape of a human stomach.

Source: Author.
of responses with a certain cut-off point in the evaluation variables of the method. P values < 0.05 were considered significant.

Ethical aspects

The study was submitted to the Ethics and Research Committee of Centro Universitário Unichristus, to be evaluated in accordance with the norms that regulate research involving human beings, according to Resolution 466/12, of the National Health Council and was approved on December 21, 2015, under number 51295815.5.0000.5049.

RESULTS

The analysis of the demographic data showed that the mean age of the students was 21.1 years, with 29 (55.8%) females and 23 (44.2%) males. Forty-six students (88.5%) showed right hand dominance and 12 (23.1%) played video games three or more hours a week. Thirty-four (65.4%) reported they had no skill or any experience in conventional surgery, while forty-five (86.5%) reported the same in relation to video-assisted surgery (Table 1).

The results of student satisfaction evaluations showed a high degree of agreement with the presented statements with at least ninety-seven percent of the answers in the items I partially agree, and I totally agree. Of the ten statements about the training model, eight showed a level of significance (p values <0.05) (Table 2). The binomial test was used in this analysis.

The increase in median values was more pronounced between the third and fourth stages for all the assessed criteria. The comparison between the medians of the first stage (initial evaluation) and the fourth stage (final evaluation) of all the evaluation criteria of knots and stitches showed a level of significance with values of p <0.001, which statistically demonstrates the progression of the students' competence in carrying out the proposed task in a simulation environment (Table 3). The ANOVA test of repeated measures was used in this analysis.

The mean time to perform an intracorporeal knot before training was 376.30 seconds and it would be even longer if the evaluation time was not limited to 10 minutes. In the training model applied in the present study, of the 52 students tested, the mean performance time for an intracorporeal node was 389.89 seconds.

For the purpose of representing the level of learning, a laparoscopic stitch was considered in any of the stages of the training model. The learning curve showed that competence in performing the laparoscopic stitch is insignificant in the initial assessment (Stage 1) and very small in the second assessment (Stage 2), which demonstrates a clear difficulty in mastering the skill only with the training of Stages 1 and 2. In the third assessment, just over half of the students achieved competence and, in the end, ninety-nine point one percent (99.1%) of the students became competent (Graph 1).

| Statements | Scores | Total | % | p |
|------------|--------|-------|---|---|
| 1. The theoretical activities contributed to the understanding of the cognitive elements of the practice of skills. | 4 | 25 | 16.0 | 0.010 |
| 2. The materials/equipment were demonstrated and provided adequate conditions for the development of skills. | 4 | 18 | 8.7 | 0.001 |
| 3. The practical demonstrations decisively contributed to the development of skills. | 4 | 16 | 7.7 | 0.001 |
| 4. The performance of the instructor / monitor decisively contributed to the learning and development of skills. | 4 | 32 | 15.4 | 0.107 |
| 5. The feedback provided decisively contributed to the learning and development of skills. | 4 | 22 | 10.6 | 0.002 |
| 6. The number of repetitions of the exercises and the division into subcomponents in the practical activities were adequate. | 4 | 6 | 2.9 | 0.001 |
| 7. The activities were effective and allowed the proposed practices to be executed without mistakes. | 4 | 55 | 26.4 | 0.014 |
| 8. The applied teaching methodology with progressive complexity stations is adequate for learning. | 4 | 8 | 3.8 | 0.001 |
| 9. The simulation environment was adequate for learning and developing the skills. | 4 | 8 | 3.8 | 0.014 |
| 10. The previous stage contributed to the current one for the development of the skills domain. | 4 | 7 | 4.5 | 0.057 |

Score 4 = I partially agree, 5 = I totally agree, p = level of significance considering significant over 90% of the answers in scores 4 and 5.

Source: Authors.
Table 3
Medians, maximum and minimum values of the evaluation criteria and significance level of the evolution between the last and the first stage of the training model in the performance of laparoscopic knots and stitches in a simulator.

|                  | 1st Stage          | 2nd Stage         | 3rd Stage         | 4th Stage         | p      |
|------------------|--------------------|-------------------|-------------------|-------------------|-------|
|                  | Med (Max-Min)      | Med (Max-Min)     | Med (Max-Min)     | Med (Max-Min)     |       |
| Half-knots       | 0.0 (7.0 - 0.0)    | 3.0 (10.0 - 0.0)  | 9.0 (25.0 - 0.0)  | 15.0 (32.0 - 3.0) | <0.001|
| Stitches         | 0.0 (2.0 - 0.0)    | 0.0 (2.0 - 0.0)   | 1.0 (4.0 - 0.0)   | 3.0 (6.0 - 0.0)   | <0.001|
| FPMS             | 0.0 (4.0 - 0.0)    | 1.0 (4.0 - 0.0)   | 3.0 (9.0 - 0.0)   | 6.0 (12.0 - 0.0)  | <0.001|
| Adequate suture tail ends | 0.0 (2.0 - 0.0) | 0.0 (3.0 - 0.0)   | 1.0 (6.0 - 0.0)   | 3.0 (11.0 - 0.0)  | <0.001|
| Adjusted initial half-knots | 0.0 (2.0 - 0.0) | 1.0 (2.0 - 0.0)   | 2.0 (5.0 - 0.0)   | 3.0 (7.0 - 0.0)   | <0.001|
| Adjusted seq. half-knots | 0.0 (5.0 - 0.0) | 1.0 (8.0 - 0.0)   | 6.0 (13.0 - 0.0)  | 12.0 (24.0 - 1.0) | <0.001|

N=number, Med=Median, Max= maximum value, Min= minimum value, FPMS= following the previous marking of the stitches, seq=sequential, p= level of significance regarding the comparison between the 4th and 1st stages of the training model and the analyzed criteria.

Source: Authors.

DISCUSSION

The start of the training focused on learning skills in manual surgical knots, followed by training for learning surgical stitches with non-laparoscopic instruments and ending with training in laparoscopic surgical stitches is unique in the models published to date. In addition to the inclusion of successful experiences that facilitated the performance of the proposed skills, such as: the demonstration of skills in stages, the minimum number of repetitions in training, applying feedback to the training and in skills assessments and training with a view of the surgical field in three dimensions preceding it with two dimensions. It should be noted that the experiences incorporated into the training model had already been carried out by several authors18-21.

The research results showed that the medical students submitted to the training made significant progress in acquiring skills in performing laparoscopic knots and stitches in a simulation environment.

The most significant research result was the median value of the number of laparoscopic stitches in the fourth stage of the training (final evaluation of the students) equal to 3.0. The comparison of this result with those of other researches showed that the progression of the acquired skill was more than the expected one. Rosser et al. (1997) published a standardized training model for 150 surgeons, all qualified, with a mean age of 42.2 years, in the Department of Surgery at Yale University, United States of America, lasting three days. This training had six training stages, with ten repetition sections in each stage12.

The importance of acquiring the skill to perform laparoscopic knots and stitches for surgeons results in the fact that this surgical technique is necessary to perform many complex laparoscopic procedures. Failure to master this skill prevents practicing surgeons from performing more advanced procedures22, 23.

The peculiarity of the current research results from the fact that a training model for the acquisition of skills in the performance of laparoscopic knots and stitches was established using Dave’s Taxonomy and the educational theories of Miller, Eriksson, Fitts and Posner, Boud and Schon, and Ende as the basis24-28.

Boud and Schon described processes through which trainees learn from practice, knowledge, experiential learning and reflection on the practice (feedback). For Ende (1983), feedback from the instructors (teachers, preceptors) is as important as feedback from the trainees themselves29.

The sequential arrangement applied to the training model was based in part on the work of Dawidek et al., who showed evidence that incorporating direct vision in three dimensions, before indirect vision in two dimensions, in a laparoscopic simulation model, accelerated the acquisition of skills21.

Dehabadi et al. published, in 2014, a review article on the use of simulators in the acquisition of laparoscopic suture skills and concluded that simulation is a useful tool in training future laparoscopic surgeons; however, they suggested that more studies would be required to answer the question of how to maximize this benefit25.
Observational studies have indicated that laparoscopic knots and sutures can be successfully learned by surgical residents on 1 to 5 day-courses using simulators, and have shown that both students with no laparoscopic experience and trainees with previous laparoscopic experience significantly benefit from such courses.

Considering that, in 2016, Hendrie et al. compared sequential training with the simultaneous training of psychomotor and spatial visual skills to perform knots and sutures in simulators and concluded that the sequential type was faster at the beginning of the learning curve; however, it did not reduce the total training time required to achieve proficiency.

There is still no consensus on the ideal training model for acquiring skills in performing laparoscopic stitches, since the learning curves in minimally-invasive surgery are still long ones. The results obtained with this study establishes a new training model that deserves to be tested in other settings. It was evident in the initial assessment results that the students did not have any previous skills, which suggests that the training model, in fact, was relevant for the learning.

Limitations

The study population, consisting of medical students, represents a group of participants that are yet to define their future actions in the medical field, but this work aims to evaluate exactly the possibility of training in this technique for undergraduate students, considering that in the near future laparoscopic stitches will become increasingly more common. In this population, there was a high prevalence of individuals with an intent to work in the surgical field, and the results may not be generalizable to all individuals.

Further studies will be required to confirm whether the skills acquired by students are compatible with those of already experienced surgeons and how this experience can be applied to the training of surgical residents. Particularly, it is suggested that future studies use a control group to make comparisons for each stage individually.

The evaluation model comprises some learning domains, but it was not possible to evaluate all the nuances of the learning complexity and the acquisition of skills in the new technique.

CONCLUSION

The study results show that the students submitted to the systematized training model showed progression of skills at the end of the training, in performing surgical knots and stitches in a laparoscopic simulation environment. The learning curve for performing a laparoscopic stitch was attained by almost all students and the degree of student satisfaction in relation to the training model stages was very significant.

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AUTHORS’ CONTRIBUTION
We declare that all authors participated in the study conception and design, data collection, analysis, and interpretation, statistical analysis, obtaining funding, writing of the manuscript, critical review of the manuscript for important intellectual content.

CONFLICTS OF INTEREST
The authors declare no conflicts of interest.

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