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Hortense Duboureau, Mariette Renaud-Petel, Celine Klein, Elodie Haraux. Development and evaluation of a low-cost part-task trainer for laparoscopic repair of inguinal hernia in boys and the acquisition of basic laparoscopy skills. Journal of Pediatric Surgery, 2021, 56 (4), pp.674-677. 10.1016/j.jpedsurg.2020.05.044. hal-03553545

HAL Id: hal-03553545 https://u-picardie.hal.science/hal-03553545

Submitted on 9 May 2023

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Title: DEVELOPMENT AND EVALUATION OF A LOW-COST PART-TASK TRAINER

FOR LAPAROSCOPIC REPAIR OF INGUINAL HERNIA IN BOYS AND THE

ACQUISITION OF BASIC LAPAROSCOPY SKILLS

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1 INTRODUCTION

2 Laparoscopy is an essential surgical tool that is now supplanting open surgery in many indications, included those

3 in pediatric surgery [1]. Although surgical skills have traditionally been taught and learnt through companionship

4 in the operating room, this paradigm has recently been challenged by legal and ethical concerns for patient safety,

- 5 work hour restrictions, the cost of operating room time, and the risk of complications. Simulation offers a potential
- 6 solution to two conflicting demands: residents want to be trained in surgery but parents want their children to be
- 7 operated on by experienced surgeons. This has become especially true since the advent of minimally invasive
- 8 pediatric surgery; a counter-intuitive visuospatial interface and greatly reduced proprioceptive feedback create

9 specific training issues [2]. It has been shown that simulations improve the operating room performance of surgical

10 residents – especially for laparoscopy, a technically demanding procedure that requires regular practice [3].

11 Low-cost models enable laparoscopic skills to be practiced more freely [4]. We therefore developed a novel, low-12 cost model of laparoscopic inguinal hernia repair (LIHR) in boys. Congenital inguinal hernias are caused by the 13 persistence of the vaginal process. As described by Becmeur et al. [5], the laparoscopic technique reproduces each 14 of the steps in conventional surgery: dissection, division, and suture of the vaginal process at the internal inguinal 15 ring. In boys specifically, the vaginal process is freed from the vas deferens and the testicular artery and then 16 fully divided. Lastly, the peritoneum is closed with an intracorporeal knot. The objectives of the present study 17 were to evaluate this part-task trainer in LIHR and assess its value in resident training programs and, more 18 generally, in the learning of basic laparoscopy skills.

19 MATERIALS AND METHODS

20 We have conceived and designed an LIHR simulation model that can be assembled easily from low-cost, readily 21 available equipment and implemented with a user manual (Appendix 1 online and Video 1 (Video)). Firstly, a 22 plastic bottle (volume: >1 L) was cut 7 cm below the neck and 7 cm from the bottom. The intermediate part was 23 discarded. The plastic ring under the bottle cap is removed from the neck of the bottle before assembly, and kept 24 for later. The bottom part was kept for the end of the assembly. The top part of the bottle (the "funnel") was 25 turned upside down and inclined, in order to mimic the inguinal canal. A colored non-sterile surgical glove (size 26 L or XL) was applied to the funnel; the fingers were passed through the neck and cut off a few centimeters 27 below. The glove mimicked the inguinal wall; at the end of the procedure, the surgeon could check whether or 28 not the wall had been accidentally perforated. Two elastic loops (e.g. Ethiloops® or "scoubidou" lanyards) of 29 different colors were placed in the bottle neck; these respectively represented the vas deferens and the testicular 30 artery. The threads were fixed with adhesive tape (e.g. Leukoplast® S LF from BSN Medical, Hamburg, Germany). A second (transparent) surgical glove was placed over this structure, to represent the peritoneum. The end of the second glove's fingers were also cut off a few centimeters below the neck of the bottle. The plastic ring present around the neck of the bottle can be used to hold the distal part of the folded gloves and the loops. The gloves must be tight. The bottom of the bottle was then used. A small hole was made in the center of the bottom, using a pair of scissors. A resistant elastic loop or an elongated balloon was knotted around the neck of the bottle and then passed through the hole in the bottom of the bottle, in order to attach the two parts together. It is important to place the neck of the bottle at an angle and to tape it tightly to the laparoscopic trainer.

38 We mailed an user manual and an evaluation questionnaire to all of the university medical center performing 39 pediatric surgery in France (32), to one university medical center in Belgium, and to all the other surgical units 40 in our university medical center (urology, visceral surgery, and gynecology) that used laparoscopy (Appendix 1, 41 online only). We proposed to all the surgical teams to test and to evaluate this model in order to have various 42 level of laparoscopic practitioners. We collected participant's characteristics (status (resident, expert), surgical 43 specialty), time for model construction and for the procedure (min). The evaluation questionnaire featured 11 44 items rated on a 5-point Likert scale (Table 2). The item scores were described as the median [interquartile range 45 (IQR)] and compared as a function of the level of expertise (residents vs. experts) using Student's t test. The 46 threshold for statistical significance was set to p < 0.01. We calculated an overall score by summing the median 47 scores for all but three of the items. Two of the excluded items concerned the ease of the procedure (the ease of 48 glove resection and the ease of suturing); in retrospect, we considered that they were not directly related to the 49 model's quality and were very dependent on the participant's level of expertise. The third item was the quality of 50 the view; in retrospect, we considered that this item was imprecise. We considered the model had been of value 51 when the median overall score was 4 or over.

52 –RESULTS

From April 2018 to April 2019, 55 practitioners from 10 university medical centers (34 departments, including 31 pediatric surgery departments and 3 general surgery departments) participated in the study. The participants' characteristics are summarized in Table 1. Forty-one of the 55 participants (74.6%) were pediatric surgeons. The scores given by the participants are detailed in Table 2. In both groups, all the participants managed to assemble the model and perform the training procedure.

58 The time needed to assemble the model was relatively short: 15.0 ± 6.2 minutes overall, 12.0 for the residents

and 15.0 minutes for the experts (p=0.07). The mean duration of the laparoscopy procedure was significantly

60 longer for the residents $(30.0 \pm 16.8 \text{ min})$ than for the experts $(26.5 \pm 11.7 \text{ min}; p=0.01)$.

61 The participants had a good overall impression of the model (4.0 ± 1.0) and had no difficulty in obtaining the 62 required equipment (76.3% of the participants gave a score of 5 out of 5 for this item).

The participants considered that the user manual was very easy to understand (score: (5.0 ± 0.6) and that the model was very easy to assemble (25.4 % of the participants gave a score of 4, and 49% gave a score of 5); there were no significant intergroup differences for these scores. Furthermore, the participants considered that the model was moderately easy to use (3.0 ± 0.9) and quite realistic (4.0 ± 0.9) .

67 The model was considered to be very easy to use by 7% of the participants, easy to use by 12.8%, moderately 68 easy to use by 49%, difficult to use by 23.6%, and very difficult to use by 5.4%. Middling scores were given for 69 the quality of the view (3.0), resection of the glove (3.0) and suturing (3.0). Suturing was reported more difficult 70 for the residents (with a mean score of 4.0, vs. 3.0 for the experts; p=0.01). The model's value in learning basic 71 laparoscopy skills was rated at 5.0 (5.0 for the residents vs. 4.0 for the experts; p=0.004). Although both groups 72 awarded a high score for this item, the score was significantly higher among the residents than among the 73 experts. The median overall score was 4.0 (4.1 for the residents vs. 4.0 for the experts; p=0.36); according to our 74 criterion, the evaluation was therefore positive.

75 **DISCUSSION**

Simulators are educational tools that enable physicians to repeatedly practice medical procedures in complete safety. The use of a simulator avoids the stress induced by real operating conditions [3]. Moreover, laparoscopic surgery training for residents is a major need [6,7]. Training on animals, human cadavers and high or low fidelity simulators is possible, but these models are not always widely available. The cost of simulation systems, the large number of residents (relative to the number of simulators) and the shortcomings of this type of training restrict continuing medical education for residents [6].

82 Low-cost simulation models constitute a very interesting option for surgical education, since they offer unlimited 83 access to training. However, it is essential to find an appropriate model that meets the surgeon's training needs. 84 A number of low-cost models have been described in the literature [8,9]. The main objective of the present study 85 was to evaluate a low-cost model of LIHR. Even though the majority of pediatric inguinal hernias are repaired 86 through open surgery, laparoscopic surgery is a minimally invasive treatment option. Although this operation is 87 often performed laparoscopically, we chose to model this particular procedure because it involves a variety of 88 basic laparoscopy skills. Indeed, we focused more on the precise performance of laparoscopic procedures than 89 on LIHR per se. Our trainees used the model to learn to grip, resect, suture and knot in different directions.

- 90 Our part-task trainer is easily assembled from material that is cheap and readily available. We also designed a
- 91 questionnaire so that surgeons could evaluate our model.
- 92 Firstly, we achieved our main objective; the model was evaluated by our participants as a tool for learning
- 93 LIHR and basic laparoscopy skills. The participants had a good opinion of our manual and our model,
- 94 regardless of their level of expertise and their surgical specialty. In this study, we recorded data concerning our
- 95 creation of the model, the performance of the procedure and the users' level of satisfaction. Despite the apparent
- 96 common-sense validity, our study design prevented us from formally validating the model or confirming its
- 97 ability to train surgeons effectively.
- 98 The participants considered that the procedure was moderately difficult to perform, and the suturing was a 99 little more difficult. The residents took significantly longer to perform the simulated procedure. This disparity 100 can be explained by the fact that suturing is the most technically difficult procedure and by the difference in 101 the level of expertise between the two groups. This may also be why the residents gave a higher score than the 102 experts did for the model's value in learning basic laparoscopy skills.
- Judging from the scores given by the participants, easy access to the material required to build the model is an asset of our design. Moreover, the time taken to assemble the model was acceptably short. It noteworthy that once the model had been built, it can be used to perform another procedure by fitting new gloves. Robert et al. have described a low-cost laparoscopy home training model [10] that could be combined with our model for training purposes. Building a low-cost model from easy-to-source material may enable a resident to progress by training at hospital or at home.
- 109 The study participants judged that the model was realistic. Although this plastic model clearly does not 110 simulate human tissue, it does schematically represent the main anatomical features needed to understand and 111 learn the surgical procedure. When designing the model, we tested various types of equipment. The neck of 112 the bottle was selected because it mimicked the internal inguinal ring. We also wanted to make the model 113 smaller, and so tried to build it with a smaller bottle. Unfortunately, this test was not satisfactory. Firstly, the 114 glove was not fully stretched over a smaller bottle, and the remaining folds would have hindered the 115 procedure. Secondly, the mouth of the smaller bottle was the same size as in the bigger bottle, and so did not 116 resemble the baby's anatomy. The study participants' main criticism concerned the view, with a mean score of 117 **3.3** out of 5. In retrospect, we admit that this item was too imprecise to be useful in evaluating the model, since it 118 concerned both the model and the laparoscopic trainer. Hence, we decided to exclude this item from the mean
- 119 overall score. In fact, the view in a conventional laparoscopic trainer is not optimal, since the fixed tablet camera

provides a view along a single axis; in contrast, the coelioscopy camera held by the surgical assistant can track the surgeon's movement. In our experience, repeated training with simple, nonrealistic model is more beneficial than the occasional use of a high-fidelity model.

123 It has been proven that simulation improves the operating room performance of surgical residents [11]. 124 Development of standardized training curricula is an absolutely necessity - particularly for minimally 125 invasive surgery [1]). The French National Pediatric Surgery Simulation Program was initiated in 2015 [12]. 126 Following the present study, our model was used as a training tool in this national program. We now would like 127 to validate this model as an educational tool - mainly for the acquisition of basic laparoscopic surgical skills. By 128 collating data from the French national program's annual evaluation, we also intend to study the model's 129 potential for translation into clinical practice and the retention of the learned skills over time. Repeated practice 130 with our model might accelerate the learning curve, as has been described in the literature for other models 131 [1, 13, 14].

- 132 It might be possible to extrapolate our model to other methods of congenital inguinal hernia repair (such as non-
- 133 dismembered repair, where the whole vaginal process is left in place) or to adult inguinal hernia repair (by
- 134 placing the inferior epigastric vessel either medial or lateral to the defect, so that the surgeon can also open up
- 135 the preperitoneal space).
- 136 Lastly, we hope that this model will be disseminated and will improve the surgical skills of surgical residents,
- 137 including those in developing countries where access to practical training may be more limited.
- 138

139 CONCLUSION

We developed a low-cost simulation model of LIHR for surgical training and skills acquisition. This low-cost model was evaluated positively and as an effective teaching and training tool for LIHR and basic laparoscopy skills. This type of practical work should be integrated into resident training programs. Our model has already been used in the French National Pediatric Surgery Simulation Program and might be of value in many other countries – especially developing countries.

- 146
- 147 **Declaration of Interest:** None
- 148
- 149

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 Table 1: Characteristics of the participants

Surgical specialty	UROLOGY	PEDIATRICS	VISCERAL SURGERY	GYNECOLOGY	TOTAL n (%)
EXPERTS (SENIORS/ ASSISTANTS)	4 (1/3)	25 (15/10)	0	0	29 (52.7%) (29.1/ 23.6)
RESIDENTS	7	16	2	1	26 (47.3)
TOTAL n (%)	11 (20.0)	41 (74.6)	2 (3.6)	1 (1.8)	55 (100)

Median duration [IQR] (min)	All participants (n=55)	Residents (n=29)	Experts (n=26)	р
Assembly	15.0 [10.0-16.0]	12.0 [10.0-22.7]	15.0 [10.0-15.0]	0.07
Procedure	26.5 [15.0-33.2]	30.0 [20.0-42.2]	20.0 [13.2-30.0]	0.01*
Total	43.0 [31.2-50.0]	47.5 [42.2-55.0]	33.5 [30.0-45.00]	0.006*
Median scores [IQR] (each out of 5)				
General impression	4.0 [4.0-4.2]	4.0 [4.0-5.0]	4.0 [4.0-4.0]	0.18
Realism	4.0 [3.0-4.0]	4.0 [3.0-4.0]	4.0 [3.0-4.0]	0.14
Ease of access to the equipment	5.0 [5.0-5.0]	5.0 [5.0-5.0]	5.0 [5.0-5.0]	0.30
Quality of the user manual	5.0 [4.0-5.0]	5.0 [4.0-5.0]	5.0 [4.0-5.0]	0.49
Ease of assembly	5.0 [4.0-5.0]	5.0 [4.0-5.0]	4.0 [4.0-5.0]	0.06
Difficulty of the procedure	3.0 [4.0-5.0]	3.0 [3.0-3.5]	3.0 [3.0-3.7]	0.33
Value in resident training programs	4.0 [4.0-5.0]	4.5 [4.0-5.0]	4.0 [3.7-5.0]	0.19
Value in learning basic laparoscopy skills	5.0 [4.0-5.0]	5.0 [5.0-5.0]	4.0 [4.0-5.0]	0.004*
Median overall score	4.5 [4.0-5.0]	4.75 [4.0-5.0]	4.0 [4.0-4.2]	0.36
Procedure scores [IQR] (each out of 5)		-		
Quality of the view	3.0 [2.0-4.0]	3.0 [3.0-4.0]	4.0 [2.0-4.2]	0.22
Difficulty of glove resection	3.0 [2.0-3.0]	3.0 [3.0-4.0]	3.0 [2.0-4.0]	0.50
Difficulty of suturing	3.0 [3.0-4.0]	4.0 [3.0-4.0]	3.0 [2.0-3.0]	0.01*

Table 2: Results of the evaluation