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Original Article

Description and validation of realistic and structured endourology training model

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Abstract: Purpose: The aim of the present study was to validate a model of training, which combines the use of non-biological and ex vivo biological bench models, as well as the modelling of urological injuries for endourological treatment in a porcine animal model. Material and Methods: A total of 40 participants took part in this study. The duration of the activity was 16 hours. The model of training was divided into 3 levels: level I, concerning the acquisition of basic theoretical knowledge; level II, involving practice with the bench models and level III, concerning practice in the porcine animal model. First, trainees practiced with animals without using a model of injured (ureteroscopy, management of guide wires and catheters under fluoroscopic control) and later practiced in lithiasic animal model. During the activity, an evaluation of the face and content validity was conducted, as well as constructive validation provided by the trainees versus experts. Evolution of the variables during the course within each group was analysed using the Student's t test for paired samples, while comparisons between groups, were performed using the Student's t test for unpaired samples. Results: The assessments of face and content validity were satisfactory. The constructive validation, "within one trainee" shows that were statistical significant differences between the first time the trainees performed the tasks in the animal model and the last time, mainly in the knowledge of procedure and Holmium laser lithotripsy cathegories. At the beginning of level III, there are also statistical significant differences between trainee's scores and the expert's scores.Conclusions: This realistic Endourology training model allows the acquisition of knowledge and technical and non-technical skills as evidenced by the face, content and constructive validity. Structured use of bench models (biological and non biological) and animal model simulators increase the endourological basic skills.

Keywords: Endourology, training, animal model, bench model, validation

Introduction

Nowadays the need for training in endourology is a matter of fact, specifically at the level of medical residents. Endourology training during residency has traditionally relied on live patients in the operating room under the strict supervision of an attending urologist. This apprentice-type of training requires a large caseload and often involves substantial additional operating room time devoted to education [1]. Residents training are essential because these techniques are part of the daily urological armamentarium, although the learning process has a relatively long learning curve, and in early stages the iatrogenic conditions risk is high [2], due to the fact that the endourological techniques are notably difficult to perform. The complications, which are not avoidable sometimes even in experienced hands, depends significantly on the number of procedures performed and the urologist skills [3]. Economic pressures to decrease operating times, as well as an increasingly litigious climate, have reduced the time dedicated to resident training [4-8].

For these reasons, it is becoming more and more difficult for the urologist in training to acquire experience in a time-efficient manner

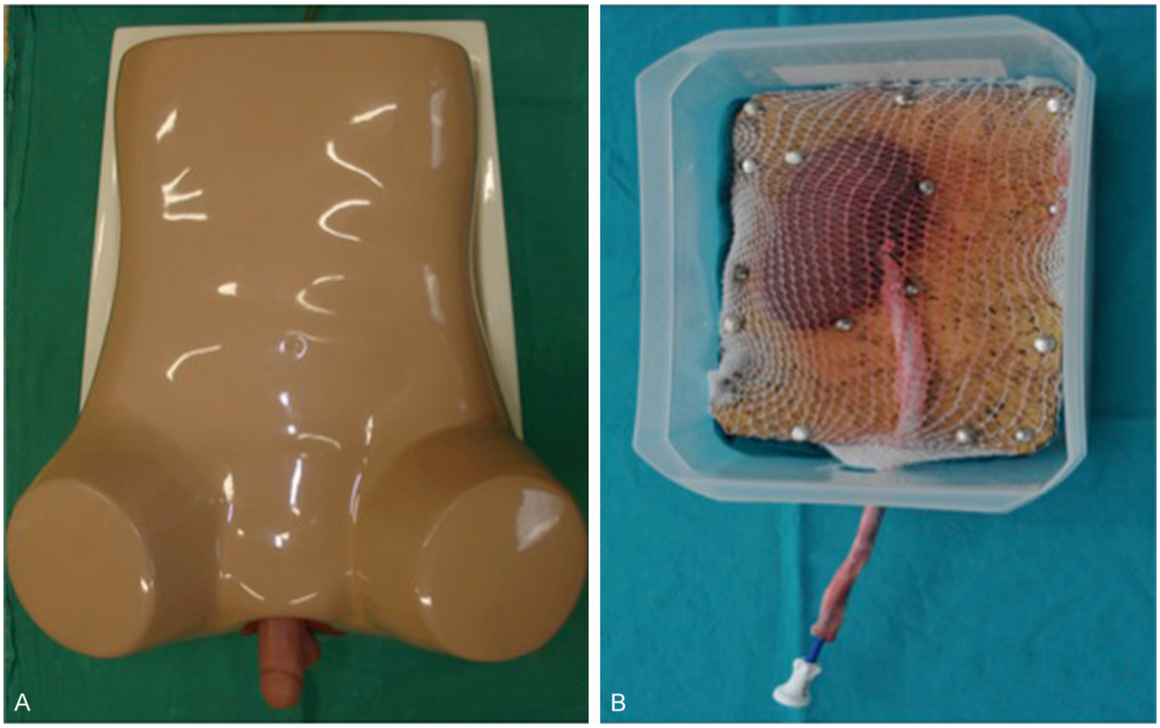

Figure 1. A. Bench model. B. Exvivo model.

[9]. In an effort to address this aspect of learning for endourology, surgical educators have developed alternative methods of training [6]. Over the last two decades, training models have been developed that are based on bench models, training with cadavers, animal models, and, recently, VR systems (virtual reality) [5].

The objective of the study was present and to validate our endourology training model. It is based on three levels, which combines the use of non-biological and ex vivo biological bench models, as well as the animal model combined with the modelling of urological injuries for endourological treatment in a porcine animal model.

Material and methods

Subjects

The participants included urology residents and a board-certified urologist with no previous experience in semi-rigid ureteroscopy (survey evaluated). A total of 40 participants took part in this study. The total duration of the activity was 16 hours (divided in four sessions). Trainees practiced in pairs, with each group being supervised by an experienced endourologist. Trainees spent an equal amount time on the simulators, live animals models, and practice the same tasks in the course of the training program.

"Principles of laboratory animal care" (NIH publication No. 86-23, revised 1985) were followed, as well as the current version of the European Union Laws on the Protection of Animals used for scientific purposes.

Training design

The training was carried out in the experimental operating theatre with all equipment needed available. To make the procedure as realistic as possible, the simulators were placed on an operating table and covered with drapes.

Training model was distributed into three levels:

Level I. Acquisition of basic theoretical knowledge. At this level, theoretical sessions (videos and lectures) related to techniques are addressed, including indications regarding ureterorenoscopy (URS) technique and complications; instrumentation; comparative anatomy; intracorporeal lithotripsy; and endourological management of ureteral stricture.

Figure 2. Practices in animal model.

The duration is approximately 20% of the total training activity duration. This level was evaluated using a test.

Level II. Practice using bench models. First of all, bench models were used (ETXY-Uro Adam©, ProDelphus, Brazil), to allow the completion of an urethrocystoscopy and the ureteral orifices cannulation with a guide wire followed by a semi-rigid URS.

Then a second simulator was used. The simulator consists in a porcine renoureteral unit from a slaughterhouse, into which ureteral lithiasis has been introduced at the mid ureteral level [10]. This simulator enables the trainee to practice laser lithotripsy, basket removal of stone fragments, and anti-migration device handling. The duration of this second level is approximately 20% of the total training activity. (**Figure 1**).

Level III. Practice with live animal models. The animal model used was a female porcine. The practices carried out using the animal model include the following:

-Urethrocystoscopy.

-Ureteral orifices cannulation and subsequent ureteroscopy.

To carry out these practices in lived porcine model, the trainees have 2 porcine models at their disposal.

Model 1. In the left nephroureteral unit, no actuation is carried out, thereby enabling the practice of basic ureteroscopy (**Figure 2**). In the right nephroureteral unit, an ureteropelvic junction (UPJ) obstruction model was created [11], 3 weeks before the training. To perform the UPJ obstruction model, first it was necessary the bipolar coagulation with laparoscopic forceps the adventitial layer of the UPJ and after partial occluding the ureteral lumen using laparoscopic approach an 3/0 polyglicolic acid ligature. The UPJ model enables the following practice techniques: the manipulation of the upper urinary tract using endoscopic-fluoroscopic control, manipulation and proper selection of guide wires and catheters, negotiation of ureteral curves and bends; instruction regarding the upper urinary tract, endourological treatment of a strictures; laser endopyelotomy, and subsequent placement of a JJ ureteral stent.

Model 2. The model 2 consists in a bilateral ureteral lithiasic animal model. These models were created surgically introducing artificial ureteral stones in both renal pelvises, one week prior to the training activity. Both ureters were stented with JJ ureteral stents to prevent renal colic and the animals were treated with analgesics during this time. So, trainees can practice laser lithotripsy, manipulation of migration of lithiasic fragments and their removal. The duration of this third level was approximately 60% of the total training activity (9,5 hours), distributed uniformly between model 1 and 2. All the practices performed in this training activity were under the supervision of an expert endourologist (more than 200 URS performed).

Evaluations

Trainees and 10 experts' endourologists had evaluated the realism of the activities using multi-item questionnaires that were specifically design for this simulation training (concerning face validity and content validity). Participants

Table 1. Face and content validation

Face validation. (Mean ± SD) (0-5)	Non biological bench model	Ex vivo biological bench model
LEVEL II		
Learning skills	4.5 ± 0.8	4.3 ± 0.6
Reality bench models	3.8 ± 1.2	4.3 ± 0.8
Ease of use	4.2 ± 0.9	4.2 ± 0.1
Allows instrumentalization?	4.1 ± 0.7	4.2 ± 0.9
	Global: 4.04 ± 0.31[a,b]	Global: 4.25 ± 0.13[a,c]
LEVEL III	Animal model	
Learning skills	4.9 ± 0.3	
Similarity to human anatomy (Reality)	3.6 ± 0.7	
Does it help to lower the iatrogenic?	4.8 ± 0.4	
Ease of use	4.4 ± 0.9	
Allows instrumentalization?	4.7 ± 0.4	
	Global: 4.48 ± 0.49[b,c]	
Content validation. (Mean ± SD) (0-5)		
Utility for training in endourology	4.8 ± 0.4	
Range of exercises	4.8 ± 0.4	
Effectiveness for skill acquisition	4.9 ± 0.3	
Level II assessment	4.2 ± 0.6	
Level III assessment	4.9 ± 0.3	
Suitable for skills assessment during training	5.0 ± 0.0	
Do you think this training model contributes to the reduction of medical iatrogenic?	5.0 ± 0.0	
	Global: 4.82 ± 0.27	

Same superscripts in the values indicate significant differences (p<0.05). [a]p<0.001*. [b]p<0.001*. [c]p<0.05*.

Table 2. Constructive validation. Global rating scale

(Mean ± SD) (0-5)	First time trainees	Last time trainees	First versus last time trainees	Experts Group	Trainees vs experts
Respect for tissue	2.1 ± 0.8	3.1 ± 0.5	p<0.001*	4.8 ± 0.1	p<0.001*
Time and motion	1.9 ± 0.9	2.9 ± 0.8	p<0.001*	4.9 ± 0.1	p<0.001*
Instrument handling	1.8 ± 0.7	2.9 ± 0.8	p<0.001*	4.7 ± 0.15	p<0.001*
Handling of endoscope	2.1 ± 1.1	3.2 ± 0.8	p<0.001*	5.0 ± 0.0	p<0.001*
Floward and procedure and forward planning	2.1 ± 0.8	3.4 ± 0.8	p<0.001*	5.0 ± 0.0	p<0.001*
Use of assistants	2.1 ± 0.8	3.5 ± 0.9	p<0.001*	5.0 ± 0.0	p<0.001*
Knowledege of procedure	2.2 ± 0.7	3.9 ± 0.7	p<0.001*	5.0 ± 0.0	p<0.001*
Instillation saline control	1.5 ± 0.6	2.2 ± 0.5	p<0.001*	5.0 ± 0.0	p<0.001*
Identification of ureteral orifices	1.8 ± 0.8	2.7 ± 0.8	p<0.001*	4.5 ± 0.2	p<0.001*
Guidewire Access to upper collecting system	1.8 ± 0.8	3.1 ± 0.6	p<0.001*	5.0 ± 0.0	p<0.001*
Completion of Holmium laser lithotripsy of stone	2.3 ± 0.6	3.5 ± 0.6	p<0.001*	5.0 ± 0.0	p<0.001*
Basket extraction of stone fragments	2.1 ± 0.4	3.3 ± 0.6	p<0.001*	5.0 ± 0.0	p<0.001*
Total scores (0-60)	24.1 ± 7.3	38.2 ± 6.5	p<0.001*	58.9 ± 1.4	p<0.001*

*Statistical significance.

showed their agreement with individual items on 5-point Likert scales (1=the worst; 5=the best).

The performances of the trainees and experts were scored using a modified global rating scale (GRS) as described by Matsumoto et al [6] in Level III. In our study, we added 5 more categories to the 7 categories used by Matsumoto. Only one expert scorer (blinded to whether it was a trainee or expert) assigned a value between 1 to 5 (1=wrong; 5=perfect) for each of the 12 categories of the modified GRS, so a constructive feedback was provided.

Construct validity was assessed in two subcategories, following the definitions of validity applied by B. Schout [12], including "within one trainee" the ability of the simulator to distinguish between the progresses of each trainee individually, and "between groups" the ability of the simulator to distinguish between different levels of experience, trainees and experts. This last subcategory was just evaluated at the beginning of this level, while the other subcategory was assessed during the whole level.

To evaluate the trainees learning curve, a cut-off point that correspond from an increase of >20% in total score average between the first and the last trainee's practices was calculated.

Statistical analyses

Variables corresponding to the scores obtained in the exercises were defined as the average ± standard error. Evolution of the variables over the length of the course within each group was analysed using the Student's t test for paired samples, while comparisons between groups, were performed using the Student's t test for unpaired samples. Internal consistency reliability of the modified global rating scale was assessed with Cronbach's alpha analysis. The level of significance in all cases was set at $p<0.05$.

Results

At the end of level I all the trainees passed their test. Each trainee performed at least four times all the scheduled tasks in the three levels of training.

The results of the face and content validity were highly satisfactory (**Table 1**). The trainees evaluated the three training models, considering that the animal model is the most suitable, secondly the ex vivo model and lastly the non-biological bench model. Statistical significant differences were found between the bench model and the exvivo model, the bench model and animal model, and exvivo model and animal model.

Internal consistency reliability of the modified Global Rate Score revealed high consistency (alpha=0.92) with Cronbach's alpha analysis. The constructive validation, "within one trainee" shows that were statistical significant differences between the first time the trainees performed the tasks in the animal model and the last time they performed it. At the beginning of level III, there are also statistical significant differences between trainee's scores and the expert's scores. The statistical significant differences were found not only in the total score but also in each task evaluated in the modified GRS score (**Table 2**).

Among the evaluated tasks, which obtained greater differences between first time and last time were "knowledge of procedure" and "use of assistants". By contrast, the lowest scores in the skills evolution of the trainees were control of irrigation during the URS and identification of ureteral orifices for cystoscopic introduce a hydrophilic guidewire. The latter parameter was also the least scored obtained in the experts group.

In our evaluation, 20 (66.6%) of trainees increased their skills above the cut-off set up in >20% between the first and the last practice performed in the animal model and evaluated by the modified GRS.

Discussion

Due to the current manifest necessity on endourological training techniques, a multitude of training programmes to improved basic skills using simulators have been developed over the last decade, principally through the use of bench models, animal models, and virtual simulators [4, 6].

The approach of our training model relies on a set of precepts described previously by other authors. The most important is that effective surgical training depends on programmes that are realistic, structured, and grounded in authentic clinical contexts that can recreate key components of the clinical experience [13]. Thus, the following factors were taken into account when developing our endourology training design model.

As described by Gallagher et al. [14], we believe that an optimal training strategy for any skill acquisition programme will ensure that the urologist has sufficient knowledge of what to do, why to do it, when and where to do it, and learn what not to do.

Furthermore, training activities should be focused on apprenticeship in specific tasks because repetitive performance of a specific task results in much better performance of that task than does general training in a variety of skills [14].

Another aspect beneficial used in our training design to the acquisition of skills is the creation of a "realistic environment", regarding the location where the activity is carried out, the instruments used, and the simulators involved. The trainees should be trained in a "stress free-environment" without time constraints or concerns about harming patients [6]. The simplest way to create a simulated environment is to work in an experimental operating room, which can be accomplished with the simulator located on the operating table, the model being draped similar to a patient, and all standard equipment and real surgical instruments being made available.

In addition, our training models allow instruction via so-called "team training" led by the urologist and the personal assistant because a well-trained and experienced assistant is as important for successful endourological procedures as an experienced urologist [3].

The combination of simulation systems used in our training model takes advantage of the benefits of each model and also reduces the adverse aspects of each model. Thus, the use of bench models in the first phase of training reduces the use of animal models, which complies with regulations and practices regarding the protection of experimental animals (principles of replacement, reduction and refinement), as well as the economic cost of the activity. In addition, bench models are useful and have therefore been validated exclusively for the first phases of training [4, 6, 15-16]. As training proceeds, a more realistic setting that can provide greater tactile feedback is necessary, which is because the porcine models are used. Finally, once the earlier phases of training have been completed, trainees are confronted with UPJ Obstruction, and ureteral lithiasic animal models.

The final parameter to take into account for a training programme is its validation, as many studies have been published regarding the utility of various simulators to improve skills in various urological activities [17]. However, these training programmes need to be validated to show that they actually are useful and that their conclusions can be extrapolated to clinical settings. This circumstance is not well documented in published studies, as there is a lack of estimated validity of training or the validity is only subjective. In their comprehensive review, Schout et al. suggested that none of the urology training models described or any previous studies have demonstrated proven validity for use in specialty training [12].

The face validity and content validity showed a high level of satisfaction between groups, and statistically significant differences were observed between the non-biological and the *ex vivo* bench models. Trainees prefer exvivo biological to non-biological bench model, because reno-ureteral porcine unit provides larger reality model and also allows best practices in upper urinary tract instrumentalization. Non-biological model does not allow ureteral dilatation during practices unlike biological model. The significant differences found between the animal model and exvivo bench model are referred mainly to the greater possibility of improve the endourological learning skills in the animal model and also allows for greater instrumentalization. These differences can be easily explained since the animal model allows complete transurethral approach from external urethral orifice, and living tissue transmits a real sense of anatomical structures, furthermore presenting the complexity related to ureteral peristalsis.

Internal consistency of the modified global rating scale used in this study was assessed with showed Cronbach's alpha revealed high consistency. In the construct validity for level III, we identify statistically significant differences (p=0.000*) with regard to the subcategory "within one trainee" in the total score. These results led us to conclude that acquisition of skills was evident. In addition, 66.6% of the trainees improved their skills over 20% between the first and the last practice evaluated. These results led us to conclude that although acquisition of skills was evident, the duration of this activity should most likely be longer. These findings have previously been described by other authors in studies comparing the distribution of practices in the form of either one long session (massed practice) or multiple, short sessions (interval practice). The study showed that interval practice was more beneficial than massed practice, and it seems that consolidation of skills cannot exclusively be achieved in a short course [14, 18]. And comparing the subcategory "between groups", we found significant differences (p=0.000*) between the novices and the experts. Furthermore, this was manifest in both the total score and in all categories evaluated.

In most previous studies of construct validity, time was the only objective parameter investigated. One potential explanation for this limited focus is that time is an easy and objective parameter to measure [19]. However, similar to other researchers, we do not believe that the time spent carrying out tasks is the most important factor or that it can be used to distinguish the level of expertise. As a result, it was not the main aim of these training models [13, 20]. All models can and should yield more objective assessment using OSATS (Objective structured assessment of technical skill), as OSATS results concern psychomotor skills such as handling of instruments; identification of ureteral orifices and cannulation; lithotripsy and basketing; and cognitive skills, such as knowledge of the procedure, respect of tissue treatment planning, troubleshooting, and peri-operative management. All of these factors appear to have more relevance than time alone [20].

Limitations of the study are mainly that the evaluation of the trainee's skills is done subjective manner by an expert and have not been developed objective measurement systems. This may always cause diversions in the evaluation.

Thus, we believe that training using the present model has great value in the initial steps before contact with a patient and for refining techniques and skills. Moreover, the integration of simulators into the surgical training CV allows residents to acquire basic surgical skills, which would otherwise lengthen the time [21].

Conclusions

This realistic Endourology training model allows the acquisition of knowledge and technical and non-technical skills as evidenced by the face, content and constructive validity. Structured use of bench models (biological and non biological) and animal model simulators increase the endourological basic skills.

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