Original Article

Face, content, and construct validity of a novel chicken model for laparoscopic ureteric reimplantation

Abhishek G. Singh*, Shrikant J. Jai, Arvind P. Ganpule, Mohankumar Vijayakumar, Ravindra B. Sabnis, Mahesh R. Desai

Department of Urology, MPUH, Nadiad, Gujarat, India

*E-mail: drabhisheksingh82@gmail.com

ABSTRACT

Introduction: Simulation-based training in laparoscopic urology is essential, as these surgeries require a different skill set. We validated a chicken model for laparoscopic left modified Lich Gregoir type of ureteric reimplantation.

Materials and Methods: Prospective observational study was conducted from August 2016 till February 2017. Thirty novice surgeons and 20 trained laparoscopic surgeons were included in the study. The relevant chicken anatomy and surgical steps were described to all the surgeons. The surgeons were asked to fill an eight-point questionnaire after finishing the procedure and score it on a scale of 1–5. The trainee's performance was also recorded by an investigator on a proforma. The investigator recorded dissection time, suturing time, quality of dissection, quality of suturing, and integrity of anastomosis on a scale of 1–5.

Results: All the participants in the study gave a mean score of 3 or more to all the questions asked, except for one question pertaining to tissue feel. Both the groups rated the usefulness of the model very highly with a mean score of 4.20 and 4.15, respectively. Difference in the time taken for dissection and suturing along with the quality of suturing was statistically significant in favor of the expert group.

Conclusions: The chicken model for laparoscopic left modified Lich Gregoir type of ureteric reimplantation is a useful, effective, cognitive training tool. This model has a face, content, and construct validity to be used as a teaching and learning tool in laparoscopic urology.

INTRODUCTION

Surgical training modules worldwide follow the Halstedian philosophy, that is, see one, do one, teach one.[1] This method of teaching relies on sheer volume of the patients a surgical trainee can operate during his training.[2-4] Progressively, the nature of surgeries, like the ones encompassing reconstructive laparoscopic urology are becoming more complex, and the patients undergoing reconstructive urological laparoscopic surgeries are sicker as compared to yesteryears.[2-4] Added to this are the factors such as, need for optimizing the operating room efficiency, and stipulated working hours in any residency program. To overcome these barriers in surgical training, the concept of simulation in surgical training has been developed over the years.[2]

Access this article online	
Quick Response Code:	Website: www.indianjurol.com
	DOI: 10.4103/iju.IJU_46_18

Simulation-based training in laparoscopic urology is essential, as these surgeries require a three-dimensional imagination of two-dimensional vision, and there is loss of haptic feedback.[5]

Various types of endotrainers, both inanimate and animal models have been described with variable degree of validity.[5-7] Validating a training model helps the trainer and trainee understand how useful the model can be in training. Validity can be face validity, content validity,

Received: 16.02.2018, **Accepted:** 24.05.2018

Financial support and sponsorship: Nil.

Conflicts of interest: There are no conflicts of interest.

criterion validity, and construct validity[2] [Table 1]. Practice on inanimate models and dry laboratory excises help the surgeon develop dexterity, coordination skills, depth perception, cutting, and suturing skills.[8] The dry laboratory experience has to be coupled with cognitive learning, in which the trainee is given information about the surgical anatomy and surgical steps.[9,10] Animal models in general are high fidelity and give a sense of tissue feel.[2,6] The major challenge remains the prediction of the transference of these skills learned in the laboratory and the improvement of cognitive learning.[10-12] We describe a chicken model for laparoscopic left modified Lich Gregoir type of ureteric reimplantation. The model represents the anatomy of left human hemipelvis, teaches the trainer skills of orientation of laparoscopic pelvic surgery, dissection, and suturing. We aimed to validate this chicken model for laparoscopic left modified Lich Gregoir type of ureteric reimplantation.

Table 1: Describing definitions of various types of validities

Face validity	Validates whether simulator does what it is proposed to do Nonexperts use the device and rate it on a scale using simple questionnaires
Content validity	It is a measure of usefulness of the trainer Experts in the field review the device and opine
Criterion validity	It validates the accuracy of the device
Concurrent validity	Concurrent validity is proved by comparing the device to an existing standard
Predictive validity	Predictive validity is the ability of the device to train an individual in such a manner, that the skills acquired can be transferred to real operating room. Testing the trainee with simulator and then in the operating room can establish this. It is difficult to test as many variables are involved
Construct validity	Construct validity is the ability of the simulator to distinguish between novice and expert. Testing large number of surgeons with variable experience can prove this; a score is given to each surgeon if the device can differentiate between the novice and an expert it is said to have good construct validity

Autorino *et al*.

Table 2a: Pro forma 1

Serial number: ....

Date: ....

Surgeon's Assessment pro forma

Questionnaire for face, content, and construct validity of a chicken model for laparoscopic left ureteric reimplantation

Likert's scale	Poor	Fair	Good	Excellent	Outstanding
Dissection	1	2	3	4	5
Orientation	1	2	3	4	5
Realism	1	2	3	4	5
Spatulation	1	2	3	4	5
Angle stitch	1	2	3	4	5
Similarity of suturing	1	2	3	4	5
Tissue feel	1	2	3	4	5
Usefulness	1	2	3	4	5

MATERIALS AND METHODS

Prospective observational study was done, during the period of August 2016 till February 2017, to validate the chicken model for the left ureteric reimplantation. Thirty novice surgeons and 20-trained laparoscopic surgeons were included in the study. Trained laparoscopic surgeons were either fellowship trained or had an experience of doing 20 or more cases. Novice surgeons were defined as surgeons who had experience of doing <5 cases or no experience of intracorporeal suturing or were routinely not assisting laparoscopic procedures. Novice surgeons were made to undergo a prior training of 20 hours in the dry laboratory. Training included the development of dexterity, coordination, cutting, and suturing skills. The relevant chicken anatomy and surgical steps were described to all the surgeons. A training video demonstration was shown to all the participants. The surgeons were asked to fill a questionnaire after finishing the procedure. The trainees were asked to rate; dissection, orientation of the model, realism, spatulation of trachea (ureter), angle stich, suturing similarity, tissue feel and usefulness of the model, on a subjective scale of 1–5 [Table 2a]. The trainee's performance was also recorded by an investigator on a proforma. The investigator was an experienced laparoscopic surgeon with an experience of >150 laparoscopic surgeries. Investigator recorded dissection time, suturing time, quality of dissection, and quality of suturing on a scale of 1–5 [Table 2b]. The investigator rated the integrity of the anastomosis after injecting saline across the anastomosis as total leak, severe leak, moderate leak, mild leak, and no leak (on a scale of 1–5) [Table 2b].

The sample size was calculated using the power and sample (PS) size Calculation Version 3.0 with the aim of comparing the outcome of the various parameters

Table 2b: Pro forma 2

Serial number: ....

Date: ....

Observers Assessment Pro forma

Questionnaire For face, content, and construct validity of a chicken model for laparoscopic left ureteric reimplantation. Dissection time (start of dissection to start of suturing): Suturing time (From beginning of angle stitch to completion of skin sutures simulating detrusorraphy)

Likert's scale	Poor	Fair	Good	Excellent		Outstanding
Dissection quality (subjectively evaluated by observer)	1	2	3	4		5
Suturing quality (subjectively evaluated by observer)	1	2	3	4		5
Integrity of anastomosis	Total leak (1)		Severe leak (2)	Moderate leak (3)	Mild leak (4)	No leak (5)

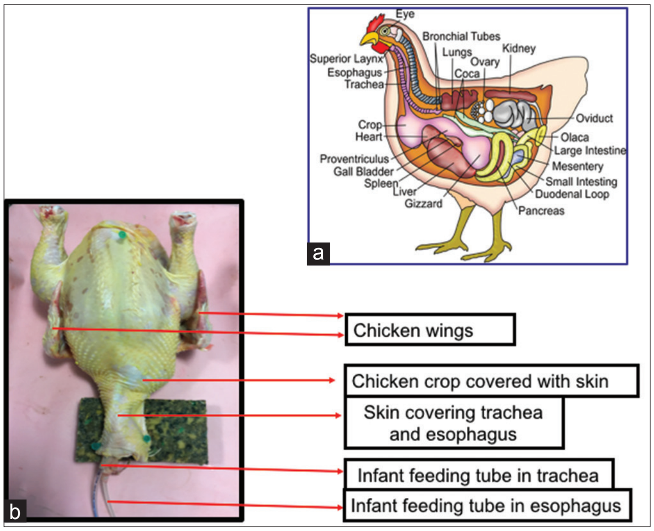


Figure 1: (a) Anatomy of a chicken. (b) a plucked chicken with infant feeding tube in trachea and esophagus

understudy (α = 0.05; power = 0.80). Statistical analysis was done using SPSS software, the difference between novice and expert group as recorded by the investigator was compared using SPSS software version 15.0 (SPSS, Chicago, IL, USA). The level of significance was set 0.05, Student's *t*-test was used to test the significance between the groups with respect to each parameter understudy.

Model construction

Relevant chicken anatomy and model preparation as explained to study participants

The chicken's upper gastrointestinal tract consists of esophagus, crop also known as ingluvies, proventriculus, and gizzard [Figure 1a]. The trachea is in close approximation with the esophagus. The assembly of esophagus and trachea lies on the cervical vertebral column.

Chicken was culled, beheaded, fur extracted, and the skin was kept intact. The chicken was kept in the supine position with the back resting on the dissection table and the headend toward the operator [Figure 1b]. An infant feeding tube was passed from the esophagus into the crop and flushed with water so that all the food particles could be evacuated and the tube was removed. Two infant feeding tubes of different colors were now, placed in the trachea and esophagus [Figure 1b]. From the esophageal tube 50 cc, water was injected and the esophagus tied with the tube [Figure 1b]. This caused distension of the crop, which would simulate the bladder. This whole assembly was placed in self-designed endotrainer box.

Box endo trainer

The box endotrainer [Figure 2a and b] used was cuboid shape, made of steel sheets, and of the size of 20 × 12 × 8 inches. The inferior surface was kept open so that the box could be placed over the chicken model, which was kept on a steel tray.

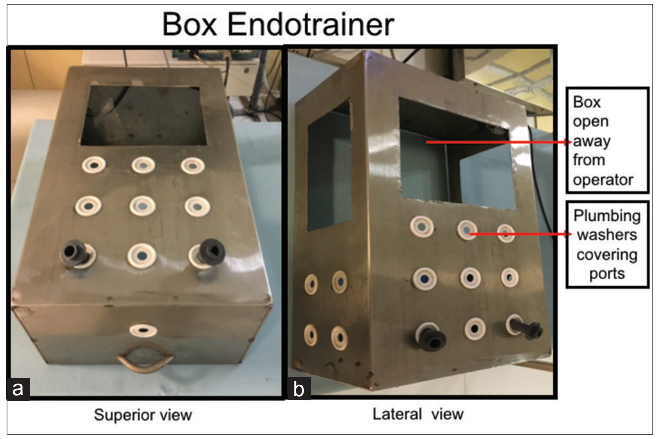


Figure 2: (a and b) Box endotrainer

Both lateral and superior surfaces were partially kept open at the ends away from the operator. The superior surface toward the operator was made of steel sheet and had nine holes carved symmetrically in the sheet. Similarly, both the lateral surfaces toward the operator were covered with steel sheet and had four holes cut out symmetrically. The surface facing toward and away from the operator was closed with steel sheet; however, the surface toward the operator had a single hole in the center covered with a plumbing rubber washer for insertion of laparoscope. All these holes were covered with rubber plumbing washers and could be used as ports. For visualization 10 mm, 30° Karl Storz™ (Tuttlingen, Germany) Laparoscope was used, which was connected to a Karl Storz™ (Tuttlingen, Germany) Single-chip camera. A 14 inches Sony™ (Tokyo, Japan) television was used as a monitor. The instruments used for training, included a Maryland grasper, a laparoscopic scissors and needle holder manufactured by R. K. Surgicals (Gurgaon, India).

Surgical planning as explained to the study participants

The participants were briefed that this model should be imagined to be a model simulating the laparoscopic anatomy of left human hemipelvis. The vertebral column simulated the left pelvic brim, the trachea simulated the left ureter, the esophagus the left common iliac vessel, and the crop simulated the bladder [Figure 3a].

Surgical Steps to be followed were as explained as below:

1. Participants were asked to make an incision along the vertebral column using a laparoscopic scissors to reflect the skin and expose the trachea [Figure 3b]
2. Circumferential dissection of the chicken trachea imagining it to be the ureter was to be done. A sling had to be passed around the chicken trachea to aid in dissection. Care had to be taken not to injure the chicken esophagus imagining it to be the common iliac [Figure 4a-d]
3. The proximal trachea had to be clipped using a metallic clip and dismembered
4. Skin over the crop had to be now incised to expose the

deeper layer, now the bluish hue of the crop appeared to be like bladder and skin-like detrusor myotomy. The crop at this stage was seen like bladder with a bluish hue of fluid [Figure 4b]

5. Trachea had to be spatulated at 6 o' clock [Figure 4c]
6. A hitch stich had to be taken, to anchor the skin adjacent to the crop, to the superior surface of the endotrainer using a hemostat
7. Crop should now be incised making a 1.5–2 cm cut on the superior surface, at this stage the crop would remain half filled with water
8. Suturing was to be started at the angle toward the operator using a silk 3–0 on RB1 needle. The needle had to be passed outside into the trachea (simulating the ureter) and then inside out on the crop (simulating the bladder) and tied [Figure 4d]
9. The left lateral wall had to be first sutured in continuous fashion till apex was reached. Now, the stent (infant feeding tube) had to be advanced into the crop. Again, starting from the angle a second stitch had to be taken and the medial wall had to be sutured till the apex. Both the sutures had to be tied to each other [Figure 5a]
10. Both the stiches had to be brought out from inside to outside the skin about 2 cm away from anastomosis [Figure 5b]. The skin had to be closed over the anastomosis-like a detrusorraphy [Figures 5c, d and 6].

RESULTS

A total of 50 participants, 30 novice surgeons and 20 trained surgeons (experts) participated in the study. Trained surgeons consisted of five fellowship-trained doctors, ten residents in their final year of residency program, who were doing and assisting laparoscopic surgeries regularly and five consultant urologists who were performing laparoscopic surgery regularly. Thirty novice surgeons included seven 1st year and twenty three 2nd year urology residency program trainees.

All the participants in the study gave a mean score of 3 or more to all the questions asked, except for one question pertaining to tissue feel which was given a mean score of 2.75 by the expert group. Across all the questions, the expert group gave a lower score than the novice group. Both the groups rated the usefulness of the model very highly with a mean score of 4.20 and 4.15, respectively [Table 3].

Construct validity of the model was calculated by comparing the novice and the expert group, with respect to, time taken for the task, quality of dissection, quality of suturing, and leak-proof anastomosis as observed by the investigator. The mean time taken for the dissection and suturing by the novice group was 9.63 ± 2.63 min and 51.83 ± 14.73 min as opposed to 6.95 ± 2.32 min and 37.15 ± 13.29 min, respectively, by the expert group. The difference in the time taken was statistically significant [Graph 1]. Quality of dissection and

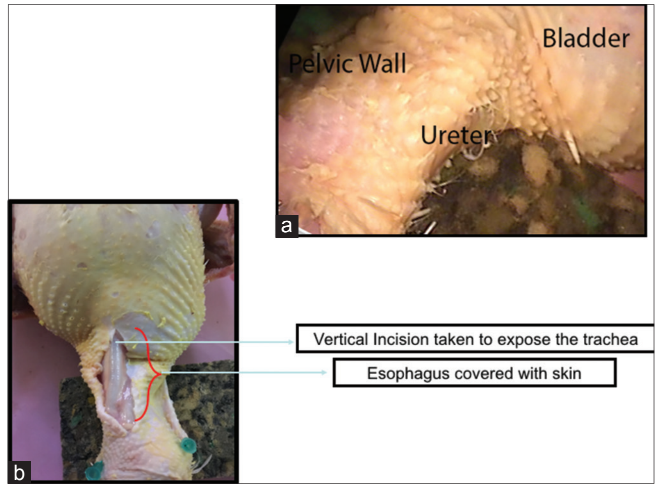


Figure 3: (a) Comparison of chicken model to human pelvis. (b) The initial incision

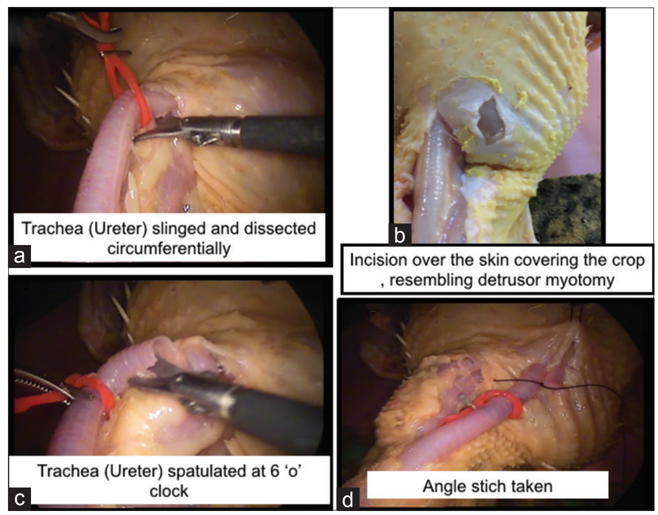


Figure 4: (a) Looped trachea (ureter). (b) Incision on crop (bladder). (c) Tracheal (ureteric) spatulation. (d) Angle stich

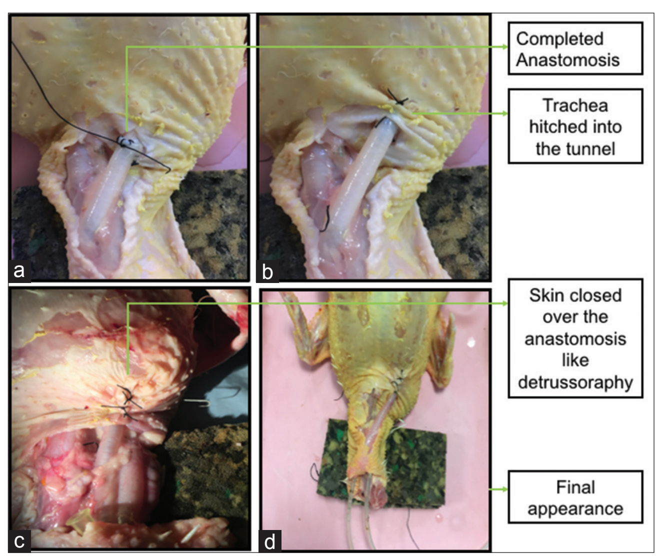


Figure 5: (a) Completed anastomosis. (b) Trachea being tunneled under skin. (c and d) Completed tunneling

integrity of anastomosis scores were better for the expert group as shown in the table [Table 4], but not statistically significant. The quality of suturing was the factor that clearly differentiated between the novice and the trained surgeons and the trained surgeons had significantly better quality of anastomosis scores as compared to the novice group [Graph 2 and Table 4].

The face validity of the model was evaluated by the surgeons of the novice group and 96% of the participants believed that the model had similar orientation and usefulness as compared to the real-time situation. In addition, 96% of participants agreed that the angle stich was similar to what was done in actual surgery. Nearly 93% and 86% of them, respectively, thought that the model had dissection

Table 3: Scores as given by the operator

Group	*n*	Mean±SD
Dissection		
Novice	30	3.57±0.72
Expert	20	3.35±0.74
Orientation		
Novice	30	4.00±0.78
Expert	20	3.05±0.75
Realism		
Novice	30	3.60±0.81
Expert	20	3.25±0.78
Spatulation		
Novice	30	4.10±0.66
Expert	20	3.80±0.52
Angle stitch		
Novice	30	4.03±0.61
Expert	20	3.75±0.44
Similarity suturing		
Novice	30	3.73±1.01
Expert	20	3.10±0.71
Tissue feel		
Novice	30	3.40±0.89
Expert	20	2.75±0.78
Usefulness		
Novice	30	4.20±0.76
Expert	20	4.15±0.58

Table highlights face and content validity of the model. SD=Standard deviation

Table 4: Scores as given by the investigator

Group	*n*	Mean±SD	*P*
Dissection time			
Novice	30	9.63±2.63	0.001
Expert	20	6.95±2.32	
Suture time			
Novice	30	51.83±14.73	0.001
Expert	20	37.15±13.29	
Dissection quality (1-5)			
Novice	30	2.63±1.18	0.151
Expert	20	3.10±0.96	
Suture quality (1-5)			
Novice	30	1.87±0.90	0.0001
Expert	20	3.30±1.17	
Integrity of anastomosis (1-5)			
Novice	30	2.37±1.24	0.090
Expert	20	3.05±1.53	

Table highlights construct validity of the model. SD=Standard deviation

and suturing similarity with re-implant surgery. The experienced group's answers [Table 2] proved that the model had content validity and agreed that it was useful, had

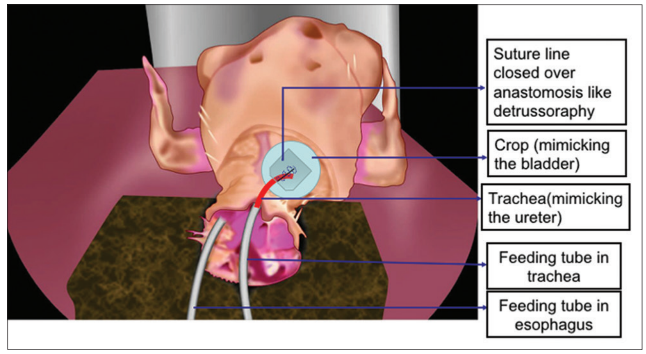
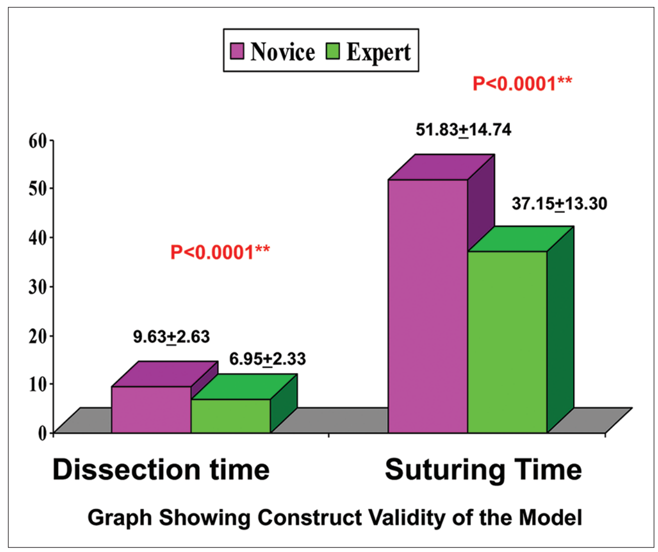
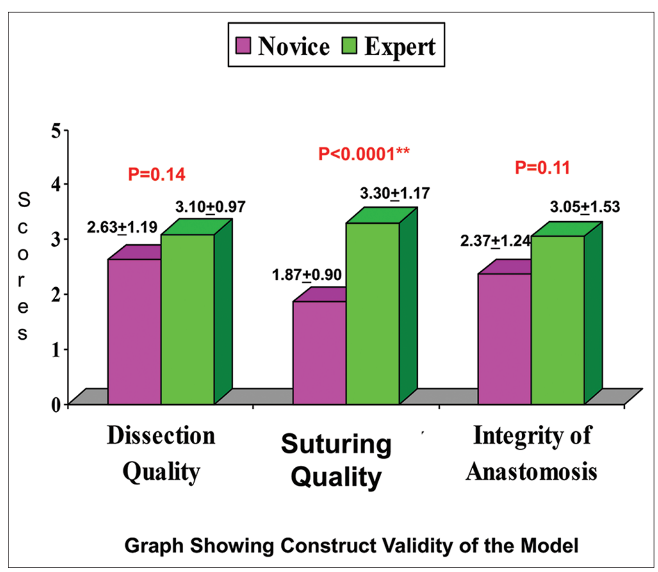


Figure 6: The diagram of completed ureteric reimplantation



Graph 1: Depicting time bound parameters observed by investigators



Graph 2: Depicting dissection quality, suturing quality, and integrity of anastomosis as observed by the investigator

real-time replication and was well oriented, that dissection could be done, and that angle stich, and spatulation were reasonable emulations of real-time situation.

DISCUSSION

The most commonly available modality of training in laparoscopic surgery is dry laboratory box endotrainer.[7] These trainers are cheap, easily available, cost-effective. Different surgeons, and institutes have their own version of the endotrainer.[7,13,14] However, merely practicing motor skills leads to incomplete training. An ideal training model should be designed to be able to train the surgeon in understanding sequence of events, give him/her adequate knowledge of anatomy and an insight into procedural surgical steps from giving him/her the motor abilities. Once this can be done for a few surgeries in a particular anatomical region, the surgeon can extrapolate these skills to other procedures. Imparting this kind of skill is time-consuming and labor intensive but is likely to shorten the learning curve on patients and decrease complication rates.[9]

Human cadaveric models where available, have the highest fidelity in training surgeons; however, they require a real-time operating room setup, whichis costly.[2] There is limited availability of cadavers, and the ones which are available are generally stored for a long period, therefore while dissection the tissues are not as compliant. Added to this are the ethical, legal, and infectious issues, which make human cadavers a less attractive option.[2]

Living animal models for training in laparoscopic surgery have been described.[10,12,15] Porcine models are the most commonly used.[6] Set up required for the living animal model is quite elaborate and most institutes cannot afford it. The use of larger living animals such as pigs is not allowed by law in many states of India and wherever permitted, the regulations are stringent.

The number of inanimate models for laparoscopic training clearly outnumbers the animal models.[6,7] Although these are reasonable training tools, they do not provide an accurate reflection of the properties of living tissue. Orientation of anatomy of a region is also something which is lacking in inanimate models.

The components of the described model in this paper include the orientation of pelvic anatomy, and orientation of the ureter and bladder in a way that it would appear in the pelvic laparoscopic view. Animal models generally focus on reconstructive part or ablative part of a procedure, like the model used for urethro-vesical anastomosis described by Laguna *et al*.[6,16-18] Our model has both the components of dissection and reconstruction. Tissue stretch or tension can be very well appreciated on freshly prepared animal models like ours.

Few models have been described for laparoscopic training using chicken. Ramachandran *et al*. described the use of a chicken model where the chicken crop and chicken esophagus was, respectively, presumed to be renal pelvis and ureter,[16] Ooi *et al*. constructed a pyeloplasty training model using reconfigured chicken skin[17] and Laguna *et al*. have described chicken model for urethrovesical anastomosis.[18]

The animal models like ours help improve the trainee compliance and motivation; these models have a definitive clinical end-point which keeps the trainee involved and keep them away from monotony. This model can differentiate between the experienced surgeon and a novice, so in effect, training benchmarks can be setup using the construct validity of the model. This may eventually help to calculate the time taken to make a surgeon ready for real-life situation.

Due to financial, legal, and ethical reasons, animal model training is on a decline.[19] In our country, poultry chicken, does not come under the jurisdiction of animal used in laboratories, hence it could be used for this purpose. The training fees of a porcine wet lab exercise is at least 1200–1400 USD for a 4–6 h session in the USA, even on subsidized basis. As opposed to this, a culled chicken is available for 3–4 USD in India and the cost of construction of our simple box trainer is about 20 USD. Instrument set from Indian manufacturer like R. K Surgicals™ cost 200 USD; these instruments can be used for 200 cases. Added to this is the cost of monitor, camera, and laparoscope. Hence, net cost of the single use of this model was about 15 USD which excluded the depreciation cost of the camera and laparoscopy system and the maintenance cost of the wet laboratory facility.

When we compare this with other laparoscopic training tools, the commercially available basic endotrainer with virtual reality aid may cost up to 5000 USD; the ones with more advanced features replicating the actual surgical scenario may cost up to 200,000 USD.[20] Using models like ours, would produce what we can call as "Pre-trained novice."[21] When these pretrained novices go on to do the actual ureteric reimplantation, they would be able to concentrate on finer issues like preventing thermal injury to ureter during dissection, gentle handling of the ureter, making a leak-proof anastomosis, etc., rather than struggling with the movement of instruments in the pelvis and facing a situation where the suturing is not possible laparoscopically.

In this study, we have validated the face, content, and construct validity of the said model. It was not possible to find out concurrent validity, as we were not able to find a similar model on an extensive literature search.

Limitations of the study

This model does not train the surgeon to deal with anatomical and physiological variations, and deals with anatomy of left human hemipelvis only. The investigator was not blinded to the performances of the study participants; this may potentially lead to bias. However, apart from subjective criteria, there were also objective criteria such as dissection time, suturing time, and leak after the anastomosis which proved the validity of the model. The predictive validity or the transference of the skill set to the real operating room situation has not been proven in the study.

CONCLUSIONS

The chicken model for laparoscopic left modified Lich Gregoir type of ureteric reimplantation is a useful, effective, cognitive training tool. This model has a face, content, and construct validity to be used as a teaching and learning tool in laparoscopic urology.

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How to cite this article: Singh AG, Jai SJ, Ganpule AP, Vijayakumar M, Sabnis RB, Desai MR. Face, content, and construct validity of a novel chicken model for laparoscopic ureteric reimplantation. Indian J Urol 2018;34:189-95.