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Development methodology of the novel Endoscopic stone treatment step 1 (EST s1) training/assessment curriculum

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Abstract:	Background Simulation based technical-skill assessment is a core topic of debate, especially in high-risk environments. After the introduction of the E-BLUS exam for basic laparoscopy, no more technical training/assessment urological protocols have been developed in Europe. Objective We describe the methodology used in the development of the novel Endoscopic Stone Treatment step 1 (EST s1) assessment curriculum. Materials and Methods The "full life cycle curriculum development" template was followed for curriculum development. A CTA was run to define the most important steps and details of RIRS, in accordance with EAU Urolithiasis guidelines. Training tasks were created between April 2015 and September 2015. Tasks and metrics were further analyzed by a consensus meeting with the EULIS board in February 2016. A review, aimed to study available

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simulators and their accordance with task requirements, was subsequently run in London on March 2016. After initial feedback and further tests, content validity of this protocol was achieved during EUREP 2016.

Results
The EST s1 curriculum development, took 23 months. 72 participants tested the 5 preliminary tasks during EUREP 2015, with sessions of 45 minutes each. Likert-scale questionnaires were filled-out to score the quality of training. The protocol was modified accordingly and 25 participants tested the 4 tasks during the hands-on training sessions of the ESUT 2016 congress. 134 participants finally participated in the validation study in EUREP 2016. During the same event 10 experts confirmed content validity by filling-out a Likert-scale questionnaire.
Conclusion
We described a reliable and replicable methodology that can be followed to develop training/assessment protocols for surgical procedures. The expert consensus meetings, strict adherence to guidelines and updated literature search towards an Endourology curriculum allowed correct training and assessment protocol development. It is the first step towards standardized simulation training in Endourology with a potential for worldwide adoption.

E-BLUS = European Basic Laparoscopic Urological Skills
EST s1 = Endoscopic Stone Treatment step 1
CTA = Cognitive Task Analysis
YAUWP = Young Academic Urologist Working Party
RIRS = Retrograde Intra-Renal Surgery
EAU = European Association of Urology
ESUT = European Section of Uro-Technology
EULIS = European Section of Uro-Lithiasis
EUREP = European Urology Residents Education Programme
FLS = Fundamentals of Laparoscopic Surgery
SAGES = American Society of Gastro-Enterological Surgeons
OSATS = Objective Structured Assessment of Technical Skills
URS = Ureterorenoscopy
KUB = Kidney-Ureter-Bladder

Development methodology of the novel Endoscopic stone treatment step 1 (EST s1) training/assessment curriculum: An international collaborative work by EAU sections

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Abstract

Background

Simulation based technical-skill assessment is a core topic of debate, especially in high-

risk environments. After the introduction of the E-BLUS (Eueopean Basic Laparoscopic Urological exam for basic laparoscopy, no more technical training/assessment urological protocols have been developed in Europe.

Objective

We describe the methodology used in the development of the novel Endoscopic Stone Treatment step 1 (EST s1) assessment curriculum.

Materials and Methods

The “full life cycle curriculum development” template was followed for curriculum development. A Cognitive Task Analysis (CTA) was run to define the most important steps and details of RIRS, in accordance with EAU Urolithiasis guidelines.

Training tasks were created between April 2015 and September 2015. Tasks and metrics were further analyzed by a consensus meeting with the EULIS board in February 2016. A review, aimed to study available simulators and their accordance with task requirements, was subsequently run in London on March 2016. After initial feedback and further tests, content validity of this protocol was achieved during EUREP 2016.

Results

The EST s1 curriculum development, took 23 months. 72 participants tested the 5 preliminary tasks during EUREP 2015, with sessions of 45 minutes each. Likert-scale questionnaires were filled-out to score the quality of training. The protocol was modified accordingly and 25 participants tested the 4 tasks during the hands-on training sessions of the ESUT 2016 congress. 134 participants finally participated in the validation study in EUREP 2016. During the same event 10 experts confirmed content validity by filling-out a Likert-scale questionnaire.

Conclusion

We described a reliable and replicable methodology that can be followed to develop training/assessment protocols for surgical procedures. The expert consensus meetings, strict adherence to guidelines and updated literature search towards an Endourology curriculum allowed correct training and assessment protocol development. It is the first step towards standardized simulation training in Endourology with a potential for worldwide adoption.

Introduction

Simulation based technical-skill assessment has been a core topic of debate, especially in high-risk environments. It was introduced in the aviation field in the early 30s with the “Link Trainer” [1]. Simulation training allows for safe and methodological acquisition of skills necessary for trainees, thereby also shortening their learning curve in this process. The first urology-specific curriculum came out in 2011, when the basic laparoscopic skills (E-BLUS) [2] exam was delivered for the first time by the European Association of Urology (EAU) and subsequently adopted worldwide. After the introduction of the E-BLUS exam, which was heavily inspired by the fundamentals of laparoscopic surgery (FLS) study carried-out by the American Society of Gastro-Enterological Surgeons (SAGES) [3], no more technical training/assessment urological protocols have been developed in Europe. With a recent surge in Endourology and stone treatment, a development of dedicated protocol-based training and assessment relating to endourological techniques was essential. While an OSATS-based assessment tool for Ureteroscopy (URS) skills has been already described [4], no structured training curriculum has yet been developed.

Objective

Aim of this paper is to describe the methodology we followed to develop the EST s1, the first step of a novel modular training/assessment curriculum for Endoscopic Stone Treatment (EST). Our goals were to develop a set of replicable, standardized, low-cost exercises, providing objective assessment and applicability to 45-60 minutes hands-on training sessions. Given the structured pathway followed, our process could work as an example for developing new training protocols with highly reliable methodology and evidence.

Materials and Methods

The "full life cycle curriculum development" template (table 1), described by Richard Satava, was followed for curriculum development. As described by the author [5], the process starts by defining the outcomes and metrics; and ends with the certification that the outcomes, as planned at the beginning, have been properly achieved. The name "full life cycle" derives straight from this concept. Our whole development process started in November 2014 and is today at the stage of validation.

Phase 1: Outcomes and Metrics

Prior to defining outcomes and metrics as described by the template, a Cognitive Task Analysis (CTA) [6,7] was run by the Endourology & Stone Treatment group of the Young Academic Urologist Working Party (YAUWP).

The CTA, as described by Clark and Estes, aims at defining the most important steps and details of a procedure and is the most appropriate way to objectively analyse it. In this case its goal was to study the details of Retrograde Intra-renal Surgery (RIRS), so CTA was run in accordance with EAU Urolithiasis guidelines [8] and in parallel with a focused updated literature review. Pre-operative, procedural, continuous variables and completion details were analysed in relation to each phase of the technique: cystoscopy, ureteroscopy, and stone fragmentation. Furthermore, indications, contraindications, equipment, patient positioning, procedural steps and "do's and don'ts" were described in relation to each of the aforementioned procedural phases.

The CTA led to a complete description of the procedure, as suggested by the EAU guidelines, and defined its main steps, as depicted in table 2. Given the detailed procedural steps, we defined a modular training system, as described in fig. 1: Basic skills with focus on navigation and basic use of the operative channels, Intermediate skills with focus on lithotripsy techniques and Advanced skills with focus on complete endoscopic lithotripsy procedures. This protocol underwent a first consensus by Delphi method with ESUT experts in February 2015.

Phase 2: Curriculum development

This phase was carried out in strict accordance with the CTA and was aimed to help the development of step 1 of the curriculum (basic skills). Training tasks were created from April 2015, until September 2015. “Indication and contraindication” information were used to structure the theoretical part of the trials, “equipment” was useful to exactly define the correct tools for each exercise, “patient positioning” and “procedure steps” were noted to define simulator requirements, while “do’s and don’ts” were critical to define errors and metrics for each training task. The first set of exercises was composed as follows: task 1, flexible cystoscopy; task 2, safety guidewire placement with rigid cystoscope; task 3, rigid ureteroscopy and working guidewire placement; task 4, access sheath placement; task 5, flexible ureterorenoscopy. After a preliminary definition of the tasks, these underwent the first test during “European Urology Residents Education Programme (EUREP)” 2015. The aims of this test were to collect tutor feedback about the possibility of completing the defined protocol during a standard 45-minutes hands-on training session. The preliminary hands-on training step-1 protocol was delivered 72 times on 4 stations, with 4 expert tutors. No major issue was reported during the preliminary test. Likert scale-based quality feedback questionnaires were collected from the participants, with focus on several aspects of this training session (fig. 2): duration of the session, new skills acquired, basic skills improvement, expectations and overall evaluation of the course. Scores went from 1 (poor) to 5 (very good).

The results were collected along with a detailed description and refinement of these tasks. The tasks and metrics were further analyzed by a consensus meeting with the “EAU Section of Urolithiasis (EULIS)” board in February 2016. Following the feedback given by experts, these were reconfigured into a total of 4 tasks (table 3): task 1, flexible cystoscopy; task 2, rigid cystoscopy; task 3, semi-rigid ureteroscopy; task 4, flexible ureteroscopy.

Phase 3: Simulator development

Based on the simulator requirements of the final task-set, a review of the existing simulators was run at Guy's Hospital, London, on March 2016. This was done in full overview of the information collected with the CTA at the beginning of the whole process. The simulators available for the trial were: Uro-Mentor (Simbionix, fig 3.A), Endo-Uro Trainer (Samed, fig 3.B), Advanced Scope Trainer (Mediskills, fig 3.C), Uro-Scopic Trainer (Limbs and Things, fig 3.D), K-Box (Coloplast, fig 3.E), KUB Model (University of Minnesota, fig 3.F). Once all the simulators had been tested, each experienced panel member independently filled out a simulator evaluation questionnaire. Panellists were asked to score with a 5-point Likert scale quality of the simulators in relation to different manoeuvres and characteristics: anatomic resemblance, bladder Visualization, instrument handling, ureteral catheterisation, ureteric navigation, semi-rigid URS and flexible URS. They were also given space for free-text comments. A final round-table discussion was then conducted to summarize their collective thoughts and findings.

Based on the results collected, two simulators (Endo-Uro Trainer by SAMED and K-Box by Coloplast) were chosen as the best fitting the needs of the protocol. The chosen models underwent some slight adaptation to allow full adoption of the task rules. The silicon bladder of the Endo-Uro Trainer was added with black marker dots to be used as targets (fig 4). The K-box was considered in one standardized configuration (fig 5), to allow for rotation, in-out and up-down movements with the flexible ureteroscope.

Phase 4: Validation

The custom-modified simulators were used for the first official test hands-on training sessions in Athens during "EAU Section of Uro-Technology (ESUT)" congress 2016, where they were used for a total of 25 one-hour sessions. Feedback from tutors was collected about the reliability of the simulators. Following the suggestions given during the tests, the black marker dots were replaced with 3mm black marker balls on the wall of the bladder models, while K-boxes were provided with numbered cavities, which allowed for an even more standardized task. After the described development process, preliminary validation of the protocol was run during EUREP 2016. In order to assess content validity of the developed protocol, ten experts from high volume stone treatment centres were asked to fill-out a Likert-score questionnaire, focused on each single task and its characteristics.

Results

The EST s1 curriculum development, from early data collection to validation, took a total of 23 months and involved EAU sections (ESUT, EULIS) and one YAUWP group, with guidance and coordination from the European School of Urology (ESU)/ESUT training group. The CTA, a detailed word document (6165 words) was structured in 5 paragraphs dedicated to the different parts of the Retrograde Intra-Renal Surgery (RIRS) procedure. Based on the CTA, a list of 3 pre-operative steps, 17 procedural steps and 5 completion steps was developed, defining the critical procedural phases to be simulated. This list was used to divide basic skills from intermediate tasks and cognitive contents (table 2). Seventy-two participants tested the 5 preliminary tasks during EUREP 2015, with sessions of 45 minutes each and the tutors reported no procedural issues. 86% of the trainees scored the training session duration as “good” or “very good”. 95% of them stated that they acquired new skills during the session (fig. 2), while 87% declared that their basic skills improved during the course. The course, based on the preliminary EST s1 curriculum, met the expectations of 92% of the participants, who scored it as overall “good” in 20% of cases and as “very good” in 77% of cases. The 5 tasks curriculum was further optimized and after feedback it was readjusted to 4 tasks. During the simulator review phase, EndoUro Trainer by SAMED and the KUB model by University of Minnesota collected the highest scores based on the set simulator requirements (table 4). Due to the nature of these tasks, K-Box was selected just for task 4 (flexible ureteroscopy).

Subsequently, the new EST s1 protocol with 4 tasks were tested by 25 participants during the hands-on training sessions of the ESUT 2016 congress, and 134 participants with different expertise ranging from 0 to >1000 real-life URS cases finally participated in the validation study in EUREP 2016. The 10 experts involved (average of 23.7 URS stone treatment procedures/month) scored individually each task from the final task list (table 5). The statement "EST s1 should be used for basic URS training & assessment" was scored with a mode of 5 (±0,3), confirming the quality of the development process. Experts suggested that the curriculum should to be applied to the 3rd year of residency (±0,8). All tasks were scored as "valid basic training tools" with a mode of 5 (task1 ±0,6; task 3 ±0,5; task 4 ±0,4) excepted for task 2, scored with a mode of 4 (±0,5). The experts considered all tasks as proper parts of the curriculum (mode 5).

Discussion

Meaning of our study

The new EST s1 protocol is the first such structured and streamlined Endourology curriculum simulation protocol, which has had collaborative input from various EAU sub-sections. The methodology has been done as a step-by-step replicable process following CTA, curriculum building, simulator review/development and feedback based protocol refinement. The result is a successful full cycle Endourology curriculum development, which has now undergone formal validation process.

Strengths and Weakness of our study

The strength of our study is the use of recognised methodology with a phased curriculum development. The CTA gave a solid background to the whole process, with a strong connection to the best achievable standards and guidelines. This allowed for a detailed curriculum building, which gave the training tasks an intrinsic validity, even before the popular "validation process", as depicted by several authors [9,10]. Indeed, even the preliminary task set tested during EUREP 2015 achieved high quality scores from the participants involved. Moreover, the process defined brought to the identification of specific simulator requirements, which lead to testing and scoring various simulators already available on the market and to finally modifying them in order to meet the requirements of the training curriculum.

This whole process successfully allowed the clinicians to wisely choose what was best fitting their needs, instead of simply using the plethora of available simulators. We consider this as one of the most important goals of our work, which should be considered as a priority for any curriculum development process.

In consideration of the expert involvement and of the scientific background given by the CTA, we acknowledge that our basic protocol has already achieved content validity, which has been anyway confirmed by the scores given by experts during EUREP 2016. Our statement is strengthened by the concept of "basic" surgical training curriculum, which is a set of basic skills that can be easily found or replicated in any procedure of similar nature. The analogy is equivalent to the E-BLUS, which contains simple skills such as cutting, bi-manual dexterity, knot tying, that are common to any laparoscopic procedure in urology, general Surgery and gynaecology. The same way, EST s1 tasks focus on navigation and basic use of operative channels, skills that can be found in urological endoscopy, but also in gastrointestinal or gynaecological endoscopy. Moving to more complex procedural steps, training becomes more specialty specific, just like happens for laparoscopy.

For complete endourology training, technical skills with a validated curriculum need to be supplemented with theoretical background, patient specific information and non-technical skills [7], which can help in training and assessment of communication skills in high stress or emergency situations. Cognitive information about the procedure were analysed and collected in a dedicated theory module by the educational group of the European Section of Urolithiasis, following the latest guidelines on this topic. The module will be integrated inside the curriculum as an addendum to the technical part. Non-technical skills related to the EST s1 protocol have not yet been analysed, even though their assessment can improve behaviour, team working and communication in these anxiety driven stressful situations [11,12]. Up to now, no weaknesses have been identified in the process, which appeared to flow smoothly and in full collaboration between different entities. The data collection from EUREP16 will eventually confirm the quality of the whole study, by integrating the already achieved content validity with face and construct validity.

Area of Future research

Although EST s1 is the first step in the integration of simulation in the Endourology curriculum, validation and further work with intermediate and advanced steps will be necessary for a comprehensive curriculum. Once this is established, subsequent work should involve fellowship in a recognised training programme in an Endourology unit.
From the information collected with the CTA and thanks to the preliminary expert consensus meetings, we already know that the intermediate step will focus on stone treatment, while advanced step will focus on full procedures and complication mastery. This work and the acquired methodology will allow for a faster development of the training protocols. Simulators enhance acquisition of skills thereby improving surgical training. The optimal duration and level of training needs to be targeted on trainee requirements and available resources. A modular training structure using low and high fidelity simulators that is realistic yet cost effective seems to be the best model for increased uptake and worldwide adoption.

Conclusion

The process summarized in this paper is a reliable and replicable methodology that can be followed to develop training/assessment protocols for any surgical procedure. The expert consensus meetings, strict adherence to guidelines and updated literature search towards an Endourology curriculum have allowed successful the achievement of content validity for the EST s1 training and assessment protocol. It is the first step in standardized simulation training in Endourology with a potential for worldwide adoption.

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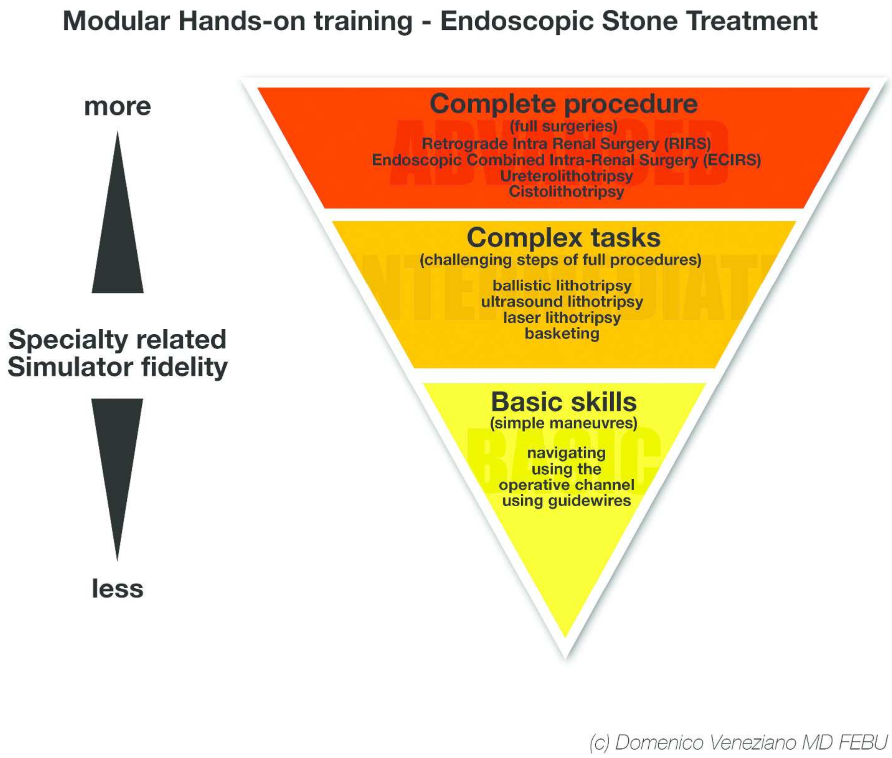

Fig 1: Modular Hands-on Training template for Endoscopic Stone Treatment

299x250mm (300 x 300 DPI)

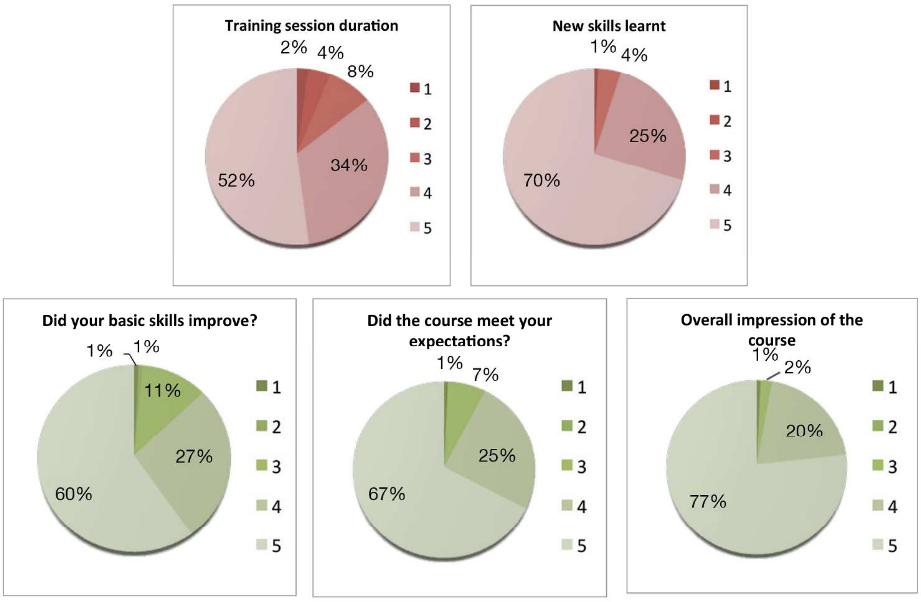

Fig 2: Likert-scale quality feedback results from EUREP 2015

208x135mm (300 x 300 DPI)

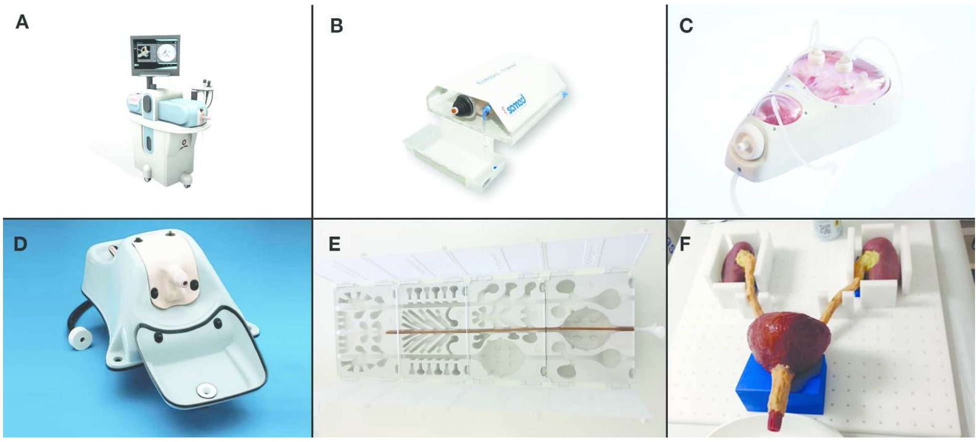

Fig.3: The simulators tested for the requirements set during EST s1 development

209x93mm (300 x 300 DPI)

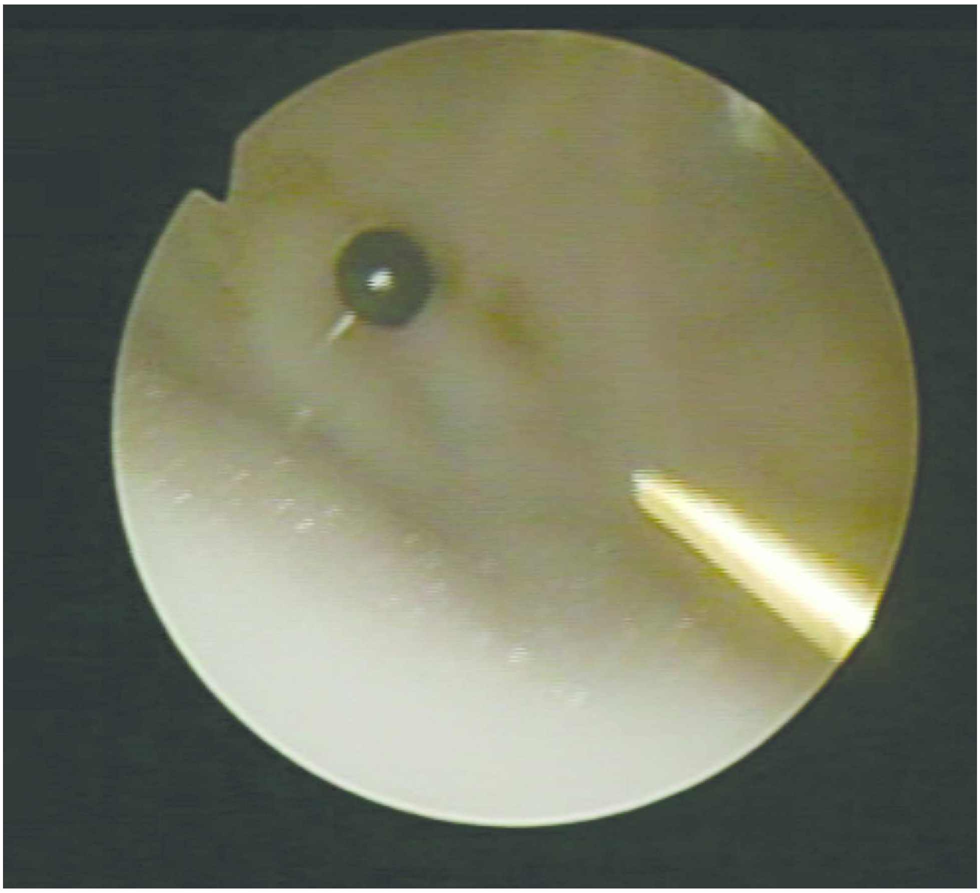

Fig 4: The black balls used as targets in the synthetic bladder.

174x158mm (143 x 143 DPI)

Fig 5: The K-Box in the standardized EST s1 configuration, with numbered cavities.

1727x1151mm (72 x 72 DPI)

WHAT	Outcomes & Metrics	Curriculum development	Simulator development	Validation studies	Implement Survey Training Certification	Issue Certification
HOW	Consensus Conference	Standard curriculum template	Engineering physical simulator	Standard validation template	Current procedures	Issue Mandates and Certificates
EST s1	nov 2014 YAUWP CTA feb 2015 ESUT meeting Davos	apr 2015 cognitive/HoT development sept 2015 preliminary test EUREP15 feb 2016 EULIS consensus	mar 2016 simulator review jun 2016 simulator adaptation jul 2016 simulator test ESUT16	sept 2016 validation EUREP16 Dec 2016 EULIS consensus	mar 2017 final tests EAU17 2017 ART in flexible	sept 2017 first exams EUREP15

Table 1: The "full-life cycle curriculum development" template adapted to the EST s1 development

337x227mm (143 x 143 DPI)

Retrograde Intra-Renal Surgery procedural steps.	
Pre-operatory phase *1. Check patient-related details (correct patient, indication, allergies, culture, antibiotics, anticoagulants)* *2. Check material-related details (equipment up to date, presence materials, settings diathermy, irrigation fluid)* *3. Patient preparation (positioning, disinfection, sterile drapes)*	**Continuous variables procedural phase** **1. Change of instruments during procedure** **2. Orientation in the bladder** **3. Regulation of irrigation and emptying bladder** 4. Maintenance of visibility 5. Intra-renal pressure awareness 6. Identification of urotelial injuries
Procedural phase (RIRS) **1. Assembling instruments and connecting tubes** **2. Adjustment of light settings, focus camera, white balance** **3. Instillation of lubricant into meatus and introduction of the cystoscope** **4. Inspection bladder including orientation, identification of orifices and eventual bladder tumors** **5. Insertion of ureteric catheter** **6. Retrograde pyelography** **7. Ureteral mapping (identification of stones/strictures/filling defects)** **8. X-ray guided placement of the guidewire (safety guidewire, X-ray safety precautions)** **9. Semi-rigid ureteroscopy (inspection of the ureter)** 10a. In case of a ureteric stone, proceed with fragmentation (laser/ballistics) **10b. In case of a renal stone, placement of the working guidewire (through the semi-rigid ureteroscope)** **11. Placement of the access sheath (choosing the optimal size and length)** **12. Insertion of the flexible ureteroscope** **13. Inspection of calices** 14a. Insertion of the laser fiber (laser safety precautions, e.g. Glasses) 14b. Introduction of biopsy forceps in case of suspected lesions 15. Stone fragmentation/dusting, and basketing as appropriate 16. Double check under fluoroscopy and endoscopy for residual fragments 17. Stent placement if clinically indicated	**Completion phase** *1. Documentation of stone-free status/residual fragments* **2. Removal of instruments** *3. Ensuring bladder emptying* *5. Debriefing (check count materials and stone-specimen/biopsy, discussion complications and postoperative policy)* *6. Registration (operating report, eventual pathology file, patient file, financial registration)*

Preliminary task list	Final task list
1. Cystoscopy	**1.** Flexible cystoscopy
2. Safety guidewire placement with rigid scope	**2.** Rigid cystoscopy and safety guidewire placement
3. Rigid ureteroscopy and working guidewire placement	**3.** Semi-rigid ureteroscopy, working guidewire and access sheath placement
4. Access sheath placement	
5. Flexible uretero-renoscopy	**4.** Flexible ureteroscope navigation

Table3: Preliminary and final tasks of the EST s1 curriculum

383x99mm (143 x 143 DPI)

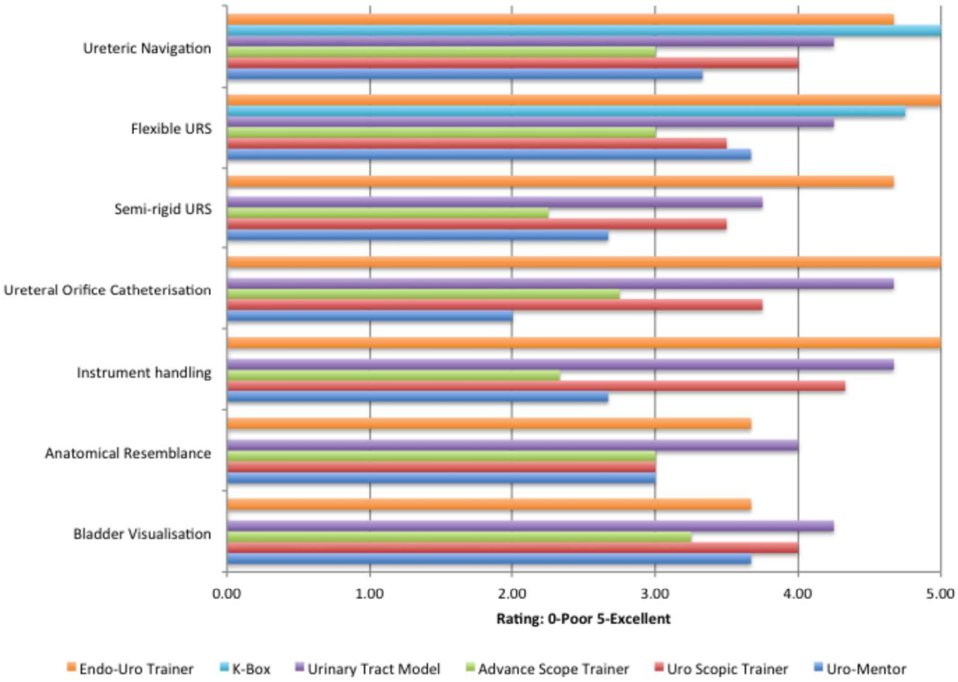

Table4: Results from the simulator review performed on March 2016

246x176mm (300 x 300 DPI)

Question	Mode (±avg SD)
Task 1 - flexible cystoscopy	
It is a valid basic training tool	5 (±0,6)
It correctly represents a flex cystoscopy	4 (±0,5)
It should be part of the EST s1	5 (±0,5)
Task 2 - rigid cystoscopy	
It is a valid basic training tool	4 (±0,5)
It correctly represents a rigid cystoscopy	5 (±0,4)
It should be part of the EST s1	5 (±0,5)
Task 3 - semi-rigid URS	
It is a valid basic training tool	5 (±0,5)
It correctly represents a semi- rigid URS	4 (±0,4)
It should be part of the EST s1	5 (±0,5)
Task 4 - flexible URS	
It is a valid basic training tool	5 (±0,4)
It correctly represents a flex URS	5 (±0,6)
It should be part of the EST s1	5 (±0,5)
Overall rating	
It should be used for basic URS training & assessment	5 (±0,3)
When would you suggest the EST s1 training/exam to be performed?	
Year of residency	3 (±0,8)

Table5: Content validity check: experts' questionnaire results

201x181mm (143 x 143 DPI)