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Definition of a Structured Training Curriculum for Robotassisted Radical Cystectomy with Intracorporeal Ileal Conduit in Male Patients: A Delphi Consensus Study Led by the ERUS **Educational Board**

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Abstract

Robot-assisted radical cystectomy (RARC) continues to expand, and several surgeons start training for this complex procedure. This calls for the development of a structured training program, with the aim to improve patient safety during RARC learning curve. A modified Delphi consensus process was started to develop the curriculum structure. An online survey based on the available evidence was delivered to a panel of 28 experts in the field of RARC, selected according to surgical and research experience, and expertise in running training courses. Consensus was defined as 80% agreement between the responders. Overall, 96.4% experts completed the survey. The structure of the RARC curriculum was defined as follows: (1) theoretical training; (2) preclinical simulation-based training: 5-d simulation-based activity, using models with increasing complexity (ie, virtual reality, and dry- and wet-laboratory exercises), and nontechnical skills training session; (3) clinical training: modular console activity of at least 6 mo at the host center (an RARC case was divided into 11 steps and steps of similar complexity were grouped into five modules); and (4) final evaluation: blind review of a video-recorded RARC case. This structured training pathway will guide a starting surgeon from the first steps of RARC toward independent completion of a full procedure. Clinical implementation is urgently needed.

Patient summary:

Robot-assisted radical cystectomy (RARC) is a complex procedure. The first structured training program for RARC was developed with the goal of aiding surgeons to overcome the learning curve of this procedure, improving patients' safety at the same time.

Keywords

Curriculum; Learning curve; Radical cystectomy; Robot-assisted surgery; Training

Radical cystectomy (RC) represents the gold standard for surgical management of organ-confined muscle-invasive bladder cancer and refractory non–muscle-invasive disease [1]. Owing to the surgical morbidity related to the open RC approach [2], the minimally invasive technique has been introduced in an attempt to improve patient outcomes. In the last decades, robot-assisted RC (RARC) increased exponentially, overtaking open RC [3]. Despite RARC being probably the most complex urological procedure with a non-negligible learning curve [4] and high complication rate, no training program is currently available to assist surgeons during their learning process. To overcome this issue, we developed the first structured training program for RARC, with the ultimate goal of improving patient's safety during the learning phase of the surgeon.

The structure of the curriculum was defined relying on a modified Delphi consensus process [5]. Using Google Forms (https://www.google.com/intl/it/forms/about/), a web-based survey (Supplementary material) based on the available evidence was generated and delivered to a panel of 28 experts in the field of RARC. Experts were selected according to their extensive experience in robotic surgery, the impact and number of their publications on robotic surgery, and their surgical training and expertise in running training courses in the field of RARC. For simplicity, the web-based survey focused exclusively on RARC for male patients with intracorporeal ileal conduit. Consensus was defined as 80% agreement between responders. Frequency and proportions were used to describe the outcomes of the survey.

The response rate in the first Delphi round was 96.4% (27/28). Consensus was reached in several areas assessed (Table 1). Unanimous agreement was reached on the statement that the adoption of a standardized curriculum for training can improve clinical outcomes during RARC learning curve and the established structure of the robot-assisted radical prostatectomy (RARP) curriculum [6] should be applied to the RARC curriculum. The panel agreed on the eligibility criteria for a trainee who should have previous experience with RARP, defined as full surgical autonomy in performing RARP, regardless of the number of procedures performed. Moreover, the trainee should have a minimum table-side assistance experience of 10 RARCs before beginning the curriculum. The structure of the RARC curriculum was divided into four main phases (Fig. 1). The first phase consisted of theoretical training, including e-learning and case observation. The second phase consisted of 5-d preclinical simulation-based training, including simulation-based activity using models with increasing complexity (ie, virtual reality, and dry- and wet-laboratory exercises) and nontechnical skills training session. In the dry laboratory, synthetic hydrogel models are used to improve suturing skills and simulate ureteroileal and bowel anastomosis. In the wet

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laboratory, cadaveric canine and living porcine models are used for simulation of the full case procedure and of vascular and bowel injury. Each trainee's performance is assessed in an objective fashion relying on a set of five Da Vinci skills simulator exercises [7] before (baseline assessment) and after (final assessment) the training session. The third phase consisted of *clinical modular training* of at least 6 mo at the host center. An RARC case was divided into 11 steps, defined as discrete segmental units of surgery in chronological order. There was high agreement regarding the progression of the trainee through the different steps that must follow a modular pattern according to the level of complexity of each step. Therefore, each step's complexity was ranked using a scale from 1 (easy) to 5 (complex), and steps with similar complexity were grouped together into five modules, defined as a unit of the same complexity regardless of chronological order. The fourth phase consisted of the *final evaluation*, based on the blind review of a video-recorded RARC case.

The increasing adoption of robot-assisted surgery in urological field also for RC calls for the development of standardized and validated training programs in order to improve patient outcomes during the learning process of this complex surgical procedure. The increasing focus on patients' safety is bringing surgical robotic training more and more out of the operating room and has forced mentors to move away from the Halstedian surgical training program of "see one, do one, teach one," where patients are inevitably exposed to an increased risk of suboptimal outcomes. Under these premises, we developed the first available structured curriculum for RARC with intracorporeal ileal conduit. This structured training program is in line with those proposed by the European Association of Urology Robotic Urology Section (ERUS) for RARP [6] and robot-assisted partial nephrectomy [5]. Theoretical and preclinical simulation-based training comprises the key elements. The latter allows replacement of a real patient with virtual, synthetic, and animal models in order to improve technical skills of trainees and shorten their learning curve for a specific procedure. It is required before clinical training in the operating theater because it was shown to improve surgical performance significantly [7]. It is of note that high agreement was reached by the panel regarding the importance of including nontechnical skills training into the preclinical simulation-based phase, underlying that appropriate communication/confirmatory feedback with bed-side assistant, anesthetist, and theater staff are mandatory to ensure safe robotic surgical performance [8]. The core of all ERUS curricula is the modular console training, where an interaction between mentor and trainee is mandatory to allow the progression through modules of increasing complexity. The role of the mentor is pivotal to the success of this process, and appropriate experience and skills are vital: the ability to share expertise often is not innate, and the increasing need for training of mentors is being recognized [9]. Another key element is the final evaluation. Measurement of outcomes and performance-level verification become imperative. The panel reached agreement that a new specific scoring system should be developed for the RARC curriculum, based on objective and validated performance metrics, defining the steps to be completed and the errors to be avoided, to track the progression of the trainee and ensure that defined benchmarks of skills will be reached before the trainee progresses to the next level of difficulty (proficiency-based progression training) [10].

Despite its novelty, this study is not devoid of limitations. First, it was developed for male candidates for RARC with intracorporeal ileal conduit. Consequently, this curriculum is

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not applicable to female candidates for RC and cannot be used to assist surgeons during their learning process for RARC with neobladder. Second, no pilot clinical validation was provided that will ultimately show whether this ERUS curriculum will allow progression through the learning curve without a detrimental effect on the patient's clinical outcomes [5].

The first structured training pathway for RARC was developed based on an international consensus between experts. This curriculum will drive a surgeon from the first steps of RARC toward independent completion of a full procedure. Clinical implementation of this curriculum is urgently needed.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Paolo Dell'Oglio certifies that all conflicts of interest, including specific financial interests and relationships and affiliations relevant to the subject matter or materials discussed in the manuscript (eg, employment/affiliation, grants or funding, consultancies, honoraria, stock ownership or options, expert testimony, royalties, or patents filed, received, or pending), are the following: None.

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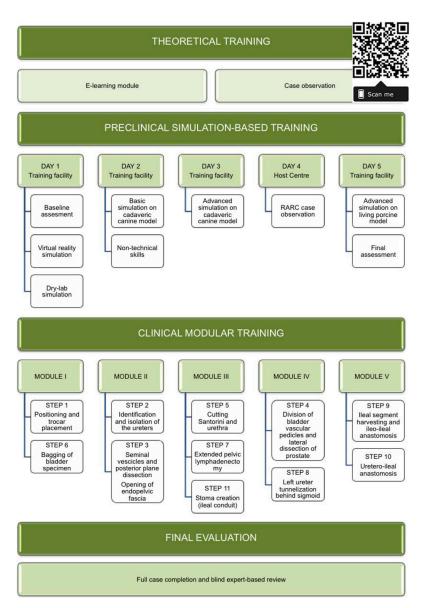


Fig. 1 –. Structure of the European Association of Urology Robotic Urology Section curriculum for robot-assisted radical cystectomy (RARC) defined by the modified Delphi consensus process.

Table 1 –

Key statements of the modified Delphi consensus process for the definition of a structured training curriculum for robot-assisted radical cystectomy

Domain	Item		Consensus
Overview	Clinical outo	comes during RARC learning curve can be improved by the adoption of a standardized for training	100% (27/27)
		hed structure of the robot-assisted radical prostatectomy curriculum should be applied C curriculum	100% (27/27)
Eligibility		nning the RARC curriculum, the candidate should have previous experience with ed radical prostatectomy	81.5% (22/27
	Before beginning the RARC curriculum, the candidate should have a minimum table-side assistance experience of $10\ RARCs$		81.5% (22/27
	To be eligible, a center should already have an ERUS host center certification		81.5% (22/27
	A total of 30 annual RARC cases is the minimum volume for a center to be eligible as a RARC curriculum host center		81.5% (22/27
Preclinical simulation-based training	Preclinical simulation-based training will have the structure presented in Figure 1		89% (24/27)
	The baseline assessment and virtual reality simulation exercises already established for the robot-assisted radical prostatectomy curriculum should be applied to the RARC curriculum		89% (24/27)
	The dry-lab exercises with synthetic hydrogel models should include the following:		89% (24/27)
	Ureteroile	eal anastomosis	96.3% (26/27
	Bowel and	astomosis	85.2% (23/27
	The animal model for the wet-lab exercises should be a cadaveric canine model and a living porcine model		81.5% (22/27
	The wet-lab exercises should include the following:		
	Case simulation on animal model		92.6% (25/27
	Vascular injury		81.5% (22/27
	Bowel injury		81.5% (22/27
	Bowel stapling		92.6% (25/27
	Vessel sealer management		81.5% (22/27
	Nontechnical skills training should include the following:		
	Decision-making		92.6% (25/27
	Emergency scenario		96.3% (26/27
	Team training		85.2% (23/27
Clinical modular training	RARC steps	were defined as follows:	100% (27/27
	I.	Patient positioning and trocar placement	
	II.	Identification and isolation of the ureters	
	III.	Incision of the Douglas pouch, freeing of the seminal vesicles, transection of vasa deferentia, opening of Denonvilliers, and preparation of the space between the prostate and the rectum. Opening of the endopelvic fascia	
	IV.	Dissection and division of the bladder vascular pedicles. Lateral dissection of the prostate (with or without nerve sparing)	
	V.	Cutting of puboprostatic ligaments, cutting of Santorini plexus with oversewing, and cutting of the urethra (avoiding tumor spillage by placing a clip on proximal urethra)	
	VI.	Bagging of bladder specimen	
	VII.	Extended pelvic lymph node dissection (can be performed after step II and before step III)	
	VIII.	Tunnelization of the left ureter behind the sigmoid	

Item Domain Consensus IX. Harvesting of the bowel segment and ileoileal anastomosis X. Ureteroileal anastomosis XI. Stoma creation (RARC with ileal conduit) RARC was divided into five modules according to the complexity of each step using a scale from I 100% (27/27) (easy) to V (complex): Module I: steps I and VI Module II: steps II and III Module III: steps V, VII, and XI Module IV: steps IV and VIII Module V: steps IX and X Progression of the trainee through the different steps must follow a modular pattern according to the 96.3% (26/27) level of complexity of each step 100% (27/27) The duration of the modular training activity should be 6-12 mo Final assessment The final assessment should be based on the evaluation of an index video by certified independent 92.6% (25/27) examiners in a blind-review process A new procedure-specific scoring system should be developed for the RARC curriculum, based on 89% (24/27) objective metrics defining the steps to be completed and the errors to be avoided The final assessment should be based on a procedure-specific scale focusing on the following steps: 81.5% (22/27) (1) dissection of bladder pedicles, (2) harvesting of the ileal segment and ileoileal anastomosis, and

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ERUS = European Association of Urology Robotic Urology Section; RARC = robot-assisted radical cystectomy.

(3) ureteroileal anastomosis