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The ERUS Curriculum for Robot-assisted Partial Nephrectomy: Structure Definition and Pilot Clinical Validation

Alessandro Larcher[a,b,c,*], *Geert De Naeyer*[c], *Filippo Turri*[b,c], *Paolo Dell'Oglio*[a,b,c], *Umberto Capitanio*[a], *Justin W. Collins*[b,d], *Peter Wiklund*[d,f], *Henk Van Der Poel*[e], *Francesco Montorsi*[a], *Alexandre Mottrie*[b,c], *on behalf of the ERUS Educational Working Group and the Young Academic Urologist Working Group on Robot-assisted Surgery*[1]

[a] *Department of Urology, Division of Oncology, Urological Research Institute, IRCCS Ospedale San Raffaele, Milan, Italy;* [b] *ORSI Academy, Melle, Belgium;* [c] *Department of Urology, Onze Lieve Vrouw Hospital, Aalst, Belgium;* [d] *Department of Urology, Karolinska University Hospital, Stockholm, Sweden;* [e] *Department of Urology, Netherlands Cancer Institute, Amsterdam, The Netherlands;* [f] *Department of Urology, Icahn School of Medicine at Mt Sinai, New York, NY, USA*

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Abstract

Background: No validated training program for robot-assisted partial nephrectomy (RAPN) exists.
Objective: To define the structure and provide a pilot clinical validation of a curriculum for robot-assisted partial nephrectomy (RAPN).
Design, setting, and participants: A modified Delphi consensus methodology involving 27 experts defined curriculum structure. One trainee completed the curriculum under the mentorship of an expert. A total of 40 patients treated with curriculum RAPN (cRAPN) were compared with 160 patients treated with standard of care (sRAPN).
Outcome measurements and statistical analysis: To define curriculum structure, consensus was defined as ≥90% expert agreement. To investigate curriculum safety, perioperative morbidity, renal function, and pathologic outcomes were evaluated. To

[1] Study collaborators: Ithaar Derweesh, Division of Urology/Department of Surgery, University of California San Diego School of Medicine, La Jolla, CA, USA; Alessandro Volpe, Department of Urology, University of Eastern Piedmont, Novara, Italy; Jihad Kaouk, Glickman Urological and Kidney Institute, Cleveland Clinic, Cleveland, OH, USA; Vincenzo Ficarra, Department of Human and Paediatric Pathology "Gaetano Barresi", Urologic Section, University of Messina, Messina, Italy; Francesco Porpiglia, Department of Urology, University of Turin, San Luigi Gonzaga Hospital, Orbassano Turin, Italy; Stefan Siemer, Department of Urology, Universittatsklinikum des Saarlandes, Homburg, Germany; Koon Rha, Department of Urology, Urological Science Institute, Yonsei University College of Medicine, Seoul, South Korea; Jens Uwe Stolzenburg, Department of Urology, University of Leipzig, Leipzig, Germany; Rajesh Ahlawat, Fortis Escorts Kidney and Urology Institute, New Delhi, India; Declan Murphy, Cancer Surgery, Peter MacCallum Cancer Centre, Melbourne, Australia; Christophe Vaessen, Department of Urology, Hopital Pitié-Salpétrière, Paris, France; Ben Challacombe, Department of Urology, Guy's Hospital, London, UK; James Porter, Department of Urology, Swedish Medical Center, Seattle, WA, USA; Daniel Moon, Division of Urology, Department of Surgery, Royal Melbourne Hospital, University of Melbourne, Parkville and Australian Prostate Cancer Research Centre at Epworth Hospital, Richmond, Australia; Nicolò Buffi, Department of Urology, Istituto Clinico Humanitas IRCCS, Humanitas University, Rozzano, Italy; Andrea Minervini, Department of Urology, AOU Careggi, University of Florence, Florence, Italy; and Achilles Ploumidis, Department of Urology, Athens Medical Centre, Athens, Greece.
* Corresponding author. URI – Urological Research Institute, Division of Experimental Oncology, IRCCS San Raffaele Scientific Institute, Via Olgettina 60, 2013 Milan, Italy. Tel. +39 02 2643 5608; Fax: +39 02 2643 7286.
E-mail address: alelarcher@gmail.com (A. Larcher).

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investigate curriculum efficacy, RAPN steps and modules attempted and completed by the trainee were evaluated. Propensity score matching identified comparable cRAPN and sRAPN cases. Mann–Whitney *U* test, chi-square test, and linear regression were used to investigate the impact of the curriculum on patient's outcome and the impact of trainee's experience on surgical independence.
Results and limitations: Consensus-based key statements defined curriculum structure. No difference was recorded between cRAPN and sRAPN with respect to intraoperative or overall and grade-specific postoperative complications, blood loss, ischemia time, postoperative estimated glomerular filtration rate, and positive surgical margins (all $p > 0.05$). Conversely, operative time was longer after cRAPN ($p < 0.0001$). The trainee completed all phases of the curriculum and the trainee's experience was associated with more steps attempted/completed and increasing complexity of module attempted/completed (all $p < 0.0001$). The limitations of the study are the enrolment of a single trainee at a single institution and the small sample size. Accordingly, the large confidence intervals observed cannot exclude inferior outcomes in case of cRAPN and further study is required to confirm safety.
Conclusions: The European Association of Urology (EAU) Robotic Urology Section (ERUS) curriculum for RAPN can protect patients from suboptimal outcome during the learning curve of the surgeon and can aid surgeons willing to start an RAPN program.
Patient summary: Patients should be aware that structured training programs can reduce the risk of suboptimal outcome due to the learning curve of the surgeon.

1. Introduction

More than 100 yr ago, Sir William Halsted established a training program for surgeons, based on the triad of educational principles consisting of knowledge of basic science, research, and seminars, and increasing patient responsibility [1]. Since then, the heart of the matter in surgical training has consisted in the increase of trainee's responsibility required to achieve independency with minimal or ideally no impact on patient's outcome [2].

In urology, patients treated during the learning phase of the surgeon are at risk of inferior outcomes relative to those treated when adequate experience is accumulated in case of open [3], laparoscopic [4], or robot-assisted radical prostatectomy (RARP) [5,6]. To counter such suboptimal outcomes observed during the learning curve of radical prostatectomy, specific training programs have been proposed [7–10] and the European Association of Urology (EAU) Robotic Urology Section (ERUS) developed a curriculum based on theoretical knowledge, preclinical simulation, and interaction between mentor and trainee, allowing for the proficiency-based progression across modules with growing complexity [11].

Although robot-assisted partial nephrectomy (RAPN) is another complex urological procedure with a non-negligible learning curve [12–14], no validated training program is currently available for this procedure. To address this void, this study aims to define the structure of a curriculum for RAPN and to provide its pilot clinical validation, with the ultimate goal of improving patient's outcome during the learning curve of the surgeon.

2. Materials and methods

2.1. Curriculum structure

The structure of the curriculum was defined using a modified Delphi consensus methodology [15]. Using Google Forms (http://www.google.com/intl/it/forms/about/), a Web-based survey (Supplementary material 1) was prepared based on the available literature on training programs in robot-assisted surgery and RAPN [2,7,9–11,16,17] and delivered to a panel of experts. A total of 30 experts in the field of RAPN were identified according to surgical experience, research and academic interest, expertise in running training courses, and participation in live-surgery cases. Consensus was defined as ≥90% agreement between the responders. An anonymized summary of the answers to the survey was circulated and used to develop a consensus synthesis of key statements approved by all responders. Frequency and proportions were used to describe the outcome of the survey.

2.2. Pilot clinical validation

One surgeon without previous experience as first-hand in open, laparoscopic, or robot-assisted major urological surgery was involved in all preclinical and clinical phases of the training program according to the structure of the curriculum outlined by the modified Delphi consensus. Theoretical and preclinical training were operational for 1 wk. Clinical training was operational at one of the ERUS Host Centres (http://uroweb.org/section/erus/erus-robotic-certified-host-centers/) in a modular proficiency-based progression fashion for 18 mo under the mentorship of a surgeon with extensive (≥300) RAPN experience using a DaVinci Xi (Intuitive Surgical Inc, Sunnyvale, California, United States) system equipped with dual console. According to the results of the modified Delphi consensus methodology, a RAPN case was divided into 10 steps, defined as discrete segmental units of the surgery in chronological order. Furthermore, each step's complexity was ranked using a scale from I (easy) to V (complex) and steps with similar complexity were grouped together into five modules, defined as unit of same complexity regardless of chronological order [7,8].

2.3. Curriculum safety

The safety of the curriculum was investigated using a comparative analysis of clinical outcomes after curriculum RAPN cases (cRAPN, defined as cases in which a trainee attempted at least a single step) versus standard-of-care RAPN cases (sRAPN, defined as procedure performed by an expert surgeon in the same institution without the involvement of a trainee). To account for any potential baseline differences among cRAPN and sRAPN patients, adjustment was performed using a 1:4 nearest-neighbour propensity score matching [18]. Propensity scores were computed using a logistic regression model with the dependent variable as the odds of receiving cRAPN and the independent variables as age at diagnosis, gender, Charlson Comorbidity Index (CCI), preoperative estimated glomerular filtration rate (eGFR), clinical tumour size, total PADUA score [19], and tumour side. A descriptive analysis of medians and interquartile ranges or frequencies and proportions was reported for continuous or categorical variables, respectively. Mann–Whitney *U* and chi-square tests were used to compare the statistical significance of differences in the distribution of continuous or categorical variables, respectively, between cases treated with cRAPN versus sRAPN. The hypothesis that cRAPN was not detrimental with respect to clinical outcomes was tested using Mann–Whitney *U* and chi-square tests to compare intraoperative, overall, and grade-specific [20] postoperative complications; estimated blood loss; operative time; ischemia time; postoperative eGFR; reduction in postoperative eGFR relative to baseline; and positive surgical margins between patients treated with cRAPN versus sRAPN. Estimates were presented using absolute median differences for continuous variables and absolute risk differences for categorical variables, respectively.

2.4. Curriculum efficacy

The efficacy of the curriculum was investigated using a descriptive analysis assessing the overall number of RAPN steps and modules attempted and completed by the trainee. Moreover, the hypothesis that trainee's experience was associated with an increase in surgical independence was tested using linear regression analysis predicting the number of individual steps and the maximal complexity of the module attempted and completed. Trainee's experience, defined for each individual patient as the number of cases in which the trainee attempted or completed at least one individual step before patient's operation, was fitted as variable of interest. Finally, the impact of the trainee's experience on the number of steps attempted and completed and the maximal complexity of the module attempted and completed was graphically represented using a polynomial smoothing function.

2.5. Statistical analyses

Statistical analyses and reporting and interpretation of the results were conducted according to established guidelines [21]. All statistical tests were performed using the RStudio graphical interface v.0.98 for R software environment v.3.0.2 (http://www.r-project.org) with the following libraries and packages: *Hmisc*, *plyr*, *stats*, *MatchIt*, *rms*, and *graphics*. All tests were two sided with a significance level set at $p < 0.05$.

3. Results

3.1. Curriculum structure

Overall, 27/30 (90%) experts completed the survey (see Study collaborators). Among the responders, all the experts agreed that the adoption of the curriculum could improve clinical outcomes and patient safety during RAPN learning curve and that the structure of the curriculum should be consistent with the already established RARP curriculum. Consensus was reached in multiple areas (Table 1). Eligibility criteria, preclinical simulation-based training, clinical modular training, and final evaluation were identified as key elements of the curriculum. To standardize RAPN technique, 10 steps were identified and were grouped into five modules of increasing complexity using a scale from 1 to 5.

The structure of the curriculum was outlined according to the consensus key statements that emerged from the Delphi process and the training pathway was divided into four main phases (Fig. 1). The first phase consisted of theoretical training, including E-learning (http://uroweb.org/education/online-education/surgical-education/robotics/theoretical-course-2/) and case observation, with the intent to provide the trainee either the robotic system- or procedure-specific necessary knowledge. The second phase consisted of preclinical training, including simulation-based activity using models with increasing complexity, namely, virtual reality and dry- and wet-lab exercises. In dry lab, synthetic hydrogel models were used for basic robotic dexterity, suturing skills, and bulldog management (Supplementary material 2, Panel A). In wet lab, harvested kidney and a living porcine model were used for full case and vascular injury simulation (Supplementary material 2, Panels B and C). The third phase consisted of clinical training, including modular console activity (Supplementary material 2, Panel D), and the fourth phase consisted of the final evaluation, based on the blind review of a video-recorded RAPN case.

3.2. Curriculum safety

After propensity-score matching, with respect to preoperative characteristics, no differences between 40 patients treated with cRAPN and 160 patients treated with sRAPN relative to age, gender, CCI, eGFR, clinical size, PADUA score, and tumour side were detected (Table 2, all $p > 0.05$). With respect to clinical outcomes (Table 3), no differences between cRAPN and sRAPN were recorded relative to intraoperative complications [10% vs 8.1%; absolute difference (AD) +1.9%; 95% confidence interval (CI) −8%, +12%; $p = 0.9$], overall (23% vs 22%; AD +0–6%; CI −14%, +15%; $p > 0.99$) or grade-specific postoperative complications, estimated blood loss (median 200 vs 200 ml; AD +20 ml; CI −30, +100 ml; $p = 0.4$), warm ischemia time (median 15 vs 15 min; AD +1 min; CI −2, +3 min; $p = 0.6$), postoperative eGFR (median 56 vs 63 ml/min/m^2; AD −6 ml/min/m^2; CI −13, +2 ml/min/m^2; $p = 0.1$), percentage of eGFR reduction relative to baseline (median −20% vs −19%; AD −1.4% CI −8.5%, +5.8%; $p = 0.7$), and positive surgical margins (5% vs 4.4%; AD +0.6%; CI −6%, +8%; $p = 0.9$). Conversely, patients treated with cRAPN had longer operative time (median 200 vs 150 min; AD +60 min; CI +37, +85 min; $p < 0.0001$) relative to sRAPN. Overall, the most common postoperative complication was fever (Supplementary material 3).

3.3. Curriculum efficacy

After completion of theoretical and preclinical training, one trainee participated in 40 cRAPN procedures in a proficiency-based modular training fashion and attempted and completed all the steps and modules of RAPN. Of the 400 RAPN individual steps available, 173 (43%) were attempted and 145 (36%) were successfully completed by the trainee (Fig. 2A). The number of steps attempted and completed changed according to the complexity of the module, ranging from 68 attempted and

Table 1 – Key statements of the modified Delphi consensus process including 27 individual experts used to define the structure of the ERUS curriculum for robot-assisted partial nephrectomy

			Consensus, % (n/N)
Overview			**Consensus, % (n/N)**
Clinical outcomes during RAPN learning curve can be improved by the adoption of a standardized curriculum for training			100 (27/27)
The established structure of the robot-assisted radical prostatectomy curriculum should be applied to the RAPN curriculum			100 (27/27)
Eligibility criteria			**Consensus, % (n/N)**
To be eligible, the candidate should have a minimum table-side assistance experience of 10 RAPN			90 (24/27)
To be eligible, the host centre should have a minimum annual volume of 40 RAPN			100 (27/27)
Preclinical simulation-based training			**Consensus, % (n/N)**
Virtual reality	The virtual reality simulation exercises already established for the robot-assisted radical prostatectomy curriculum should be applied to the RAPN curriculum		93 (25/27)
Dry lab	The dry-lab exercises should include	Basic robotic dexterity	96 (26/27)
		Suturing skills	100 (27/27)
		Bulldog management	96 (26/27)
Wet lab	The animal model for the wet-lab exercises should be a living porcine model		96 (26/27)
	The wet-lab exercises should include	Case simulation on animal model	96 (26/27)
		Vascular injury	90 (24/27)
Nontechnical skills	The nontechnical skills should include:	Decision-making	90 (24/27)
		Emergency scenario	90 (24/27)
Clinical modular training			**Consensus, % (n/N)**
Steps	RAPN was divided into 10 steps according to the chronological sequence as	Step 1: Trocar placement and specimen retrieval Step 2: Bowel/liver mobilization Step 3: Hilum control Step 4: Gerota fascia opening Step 5: US scan and tumour demarcation Step 6: Artery clamping and declamping Step 7: Tumour excision Step 8: Inner renorrhaphy Step 9: Outer renorrhaphy Step 10: Gerota fascia closure	96 (26/27)
Modules	RAPN was divided into five modules according to the complexity of each step using a scale from I (easy) to V (complex) as	Module I: Trocar placement and specimen retrieval, Gerota fascia closure Module II: Bowel/liver mobilization, Gerota fascia opening Module III: Artery clamping and declamping, Outer renorrhaphy Module IV: Hilum control, US scan and tumour demarcation Module V: Tumour excision, Inner renorrhaphy	100 (27/27)
Steps 1–3 can be performed either in case of RAPN, radical nephrectomy, or nephroureterectomy			100 (27/27)
The progression of the trainee through the different module must follow a proficiency-based modular pattern according to the complexity of each module			96 (26/27)
Final evaluation			**Consensus, % (n/N)**
The final assessment should be based on the evaluation of an index video by certified independent examiners in blind-review process using a procedure-specific evaluation scale			96 (26/27)
The final evaluation should be based on the following steps		Step 3: Hilum control Step 7: Tumour excision Step 8: Inner renorrhaphy	93 (25/27)

ERUS = European Association of Urology Robotic Urology Section; RAPN = robot-assisted partial nephrectomy; US = ultrasonography.

63 completed, for module I, to 13 attempted and nine completed, for module V (Fig. 2B).

The trainee's experience was associated with a higher number of steps attempted and completed and with increasing maximal complexity of module attempted and completed (all $p < 0.001$). After 40 cases, the estimated number of steps completed was less than eight (Fig. 3A) and the estimated maximal complexity of module completed was less than four (Fig. 3B).

4. Discussion

Clinical implementation of training in surgery is not a simple task, due to the balance between the need for increasing trainee's exposure without a detrimental effect on patient's outcome. Such equilibrium is even more delicate in the context of complex surgical procedures such as radical prostatectomy [3–6] or RAPN [12,13]. Under these premises, the current report is the first description and pilot clinical validation of a training curriculum for RAPN.

The results of this study are of utmost importance to patients and clinicians for several reasons. First, a complete training pathway was constructed based on the essentials identified by a panel of experts in the field of RAPN. This pathway can guide the trainee from theoretical knowledge across preclinical, simulation-based training including virtual reality and dry and wet lab to clinical activity. The latter represents the core of the program and is based on the

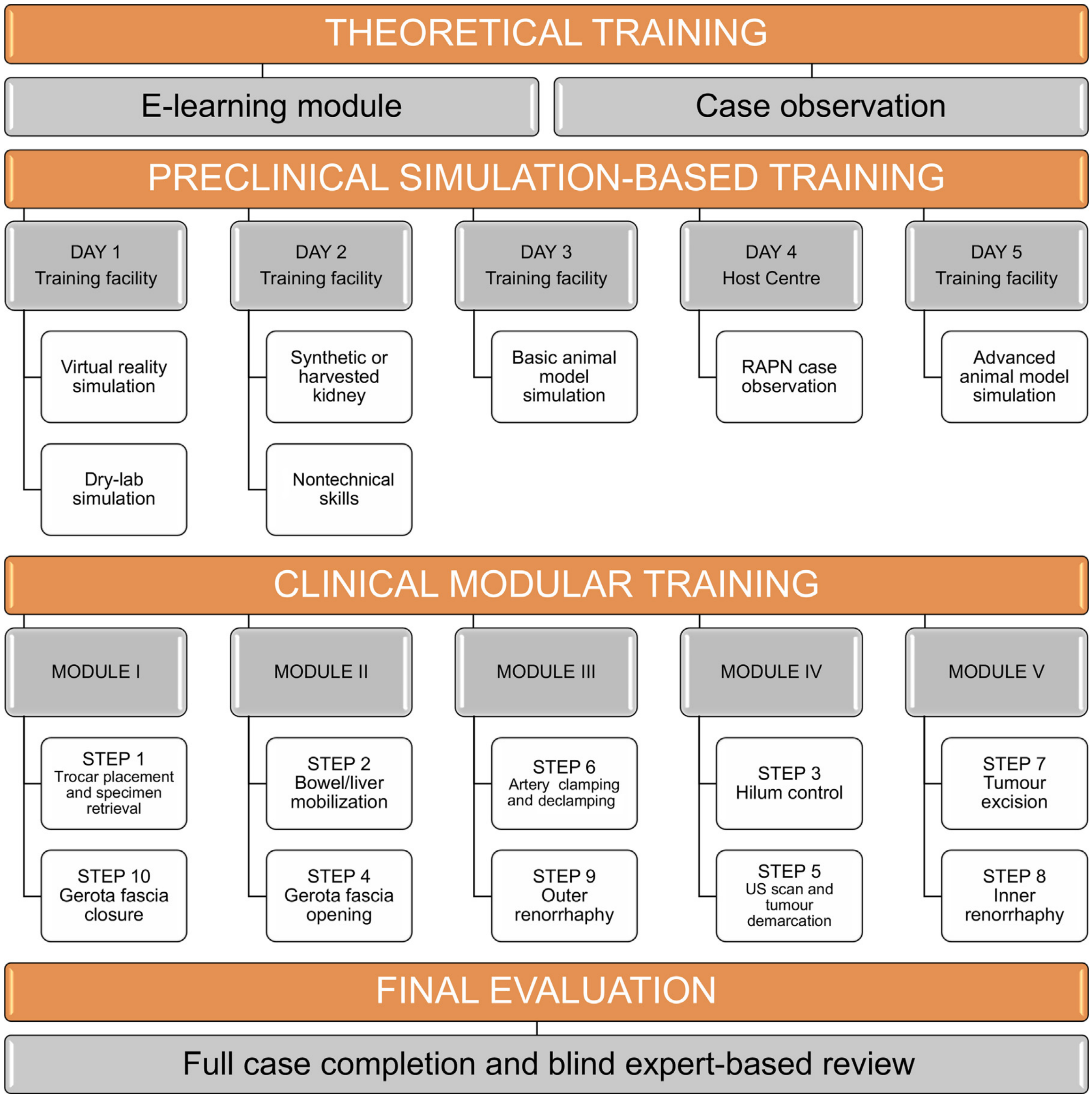

Fig. 1 – Structure of the European Association of Urology Robotic Urology Section curriculum for robot-assisted partial nephrectomy defined by the modified Delphi consensus process. RAPN = robot-assisted partial nephrectomy; US = ultrasound.

partition of a full RAPN case into steps, according to the chronological order of each unit, and into modules according to the complexity of each unit (modular training). Furthermore, the progression of the trainee through more complex modules is allowed only when the less complex ones are completed (proficiency-based progression training), relying on a model that underscores the key role of the interaction between mentor and trainee in the transition to full-case independency.

Second, the pilot clinical validation of the program was safe. In a cohort of patients comparable with respect to all the preoperative characteristics that affect RAPN clinical outcomes [22–24], patients treated in the context of the program did not experience any detrimental aftermaths in their clinical course relative to the standard of care. Specifically, no difference was recorded with respect to perioperative morbidity, early renal function, or pathologic outcomes.

Third, the pilot clinical validation of the program was effective. A trainee completed all the preclinical phases of the program and all the steps and modules of the clinical training. Moreover, the experience of the trainee was associated with increasing surgical independence. According to the modular, proficiency-based structure of the clinical activity, the easier steps and modules were independently performed more frequently relative to the more complex ones.

These key findings can be summarized as safe and effective implementation of the ERUS curriculum for RAPN, and corroborate and expand previous pivotal investigations in the setting of training in robot-assisted urologic surgery, such as the curriculum already established for RARP [11]. This study was taken as paradigm for the development of the current study and represents its forge, because the aim was the implementation of a program with a parallel

Table 2 – Preoperative characteristics of 160 patients treated with standard-of-care robot-assisted partial nephrectomy and 40 patients treated during the ERUS curriculum for robot-assisted partial nephrectomy at a single European institution after propensity-score matching for clinical characteristics, 2011–2018

Preoperative characteristics	sRAPN (*n* = 160)	cRAPN (*n* = 40)	*p* value
Age, yr			0.6
Median	63	66	
IQR	52–72	53–71	
Gender			>0.99
Male	107 (67)	27 (67)	
Female	53 (33)	13 (33)	
CCI			0.8
0	66 (41)	17 (42)	
1	36 (22)	11 (28)	
2	25 (16)	4 (10)	
≥3	33 (21)	8 (20)	
eGFR (ml/min/1.73 m^2)			0.4
Median	80	77	
IQR	65–92	63–86	
Clinical size (cm)			0.5
Median	3.6	4.1	
IQR	2.4–5.5	2.7–5.6	
PADUA score[a]			0.7
Low complexity	31 (19)	7 (18)	
Intermediate complexity	57 (36)	12 (30)	
High complexity	72 (45)	21 (52)	
Tumour side			>0.99
Left	53 (33)	14 (35)	
Right	107 (67)	26 (65)	

Data are presented as *n* (%) unless otherwise specified.
CCI = Charlson comorbidity index; cRAPN = ERUS curriculum robot-assisted partial nephrectomy; ERUS = European Association of Urology Robotic Urology Section; eGFR = estimated glomerular filtration rate; IQR = interquartile range; PADUA score = preoperative aspects and dimensions used for an anatomical classification of renal tumours; sRAPN = standard-of-care robot-assisted partial nephrectomy.
[a] Grouped in categories in the table for clarity purpose but computed in propensity-score matching as continuous variable.

structure but in a different field. Remarkably, besides face validity and educational impact, the current study also investigated clinical data using a comparative design relative to the standard of care.

The safety data presented herein are in line with previous investigations demonstrating similar patient's outcomes between cases treated by expert surgeons and cases treated by trainee in the special setting of a modular, proficiency-based training program for laparoscopic prostatectomy [7,8,25]. Notably, the current study is the first investigation expanding this finding to the scenario of training in robot-assisted surgery and in the scenario of nephron-sparing surgery. The safe completion of the clinical steps of the curriculum is even more important in the setting of partial nephrectomy, given its relatively high complications rate, ranging from 23% to 36% [19,26,27] according to the population of interest. Moreover, the consistency between perioperative outcomes observed in the current study and other investigations evaluating RAPN clinical outcomes [24,27–30] is an argument in favour of the validity of the study's findings.

It is also important to remember that cRAPN resulted in 60 min longer operative time relative to sRAPN and, although no other clinical aftermath was noted, the impact of such increase in operative time on anaesthesia, operating theatre agenda, and ultimately health care expenditures is not negligible and requires consideration when training activity is planned. For instance, assuming a cost of €32 per min of operating theatre [31], the health care expenditure increase associated with each case included in the curriculum is €1920. Is this figure inexpensive or expensive? To answer such critical questions, it is important to remember that our analysis is the first available source that allows for a direct estimation of the prolonged operative time due to a

Table 3 – Clinical outcomes of 160 patients treated with standard-of-care robot-assisted partial nephrectomy and 40 patients treated during the ERUS curriculum for robot-assisted partial nephrectomy at a single European institution after propensity-score matching for clinical characteristics, 2011–2018

Morbidity and complications	sRAPN (*n* = 160)	cRAPN (*n* = 40)	cRAPN vs sRAPN Absolute difference (95% CI)	*p* value
Intraoperative complications	13 (8.1)	4 (10)	+1.9% (−8, 12)	0.9
Overall postoperative complications	35 (22)	9 (23)	+0.6% (−14, 15)	>0.99
Complications Clavien–Dindo ≥2	13 (8.1)	4 (10)	+1.9% (−8, 12)	0.9
Complications Clavien–Dindo ≥3	9 (5.6)	2 (5)	−0.6% (−8, 7)	>0.99
Estimated blood loss (ml)	200 (100–400)	200 (100–500)	+20 (−30, +100)	0.4
Operative time (min)	150 (120–180)	200 (178–253)	+60 (37, 85)	>0.99
Renal function	**sRAPN (*n* = 160)**	**cRAPN (*n* = 40)**	**cRAPN vs sRAPN Absolute difference (95% CI)**	***p* value**
Ischemia time (min)	15 (10–19)	15 (12–20)	+1 (−2, 3)	0.6
Postoperative eGFR (ml/min/1.73 m^2)	63 (47–76)	56 (44–69)	−6 (−13, 2)	0.1
eGFR reduction (%)	−19 (−7.7, −30)	−20 (−7.1, −33)	−1.4 (−8.5, 5.8)	0.7
Pathology	**sRAPN (*n* = 160)**	**cRAPN (*n* = 40)**	**cRAPN vs sRAPN Absolute difference (95% CI)**	***p* value**
Positive surgical margins	7 (4.4)	2 (5)	+0.6% (−6, 8)	>0.99

Data are presented as median, interquartile range, and absolute median differences with specific unit of measure for continuous variables and as *n* (%) and absolute risk differences for categorical variables.
CI = confidence interval; cRAPN = curriculum robot-assisted partial nephrectomy; eGFR = estimated glomerular filtration rate; ERUS = European Association of Urology Robotic Urology Section; sRAPN = standard-of-care robot-assisted partial nephrectomy.

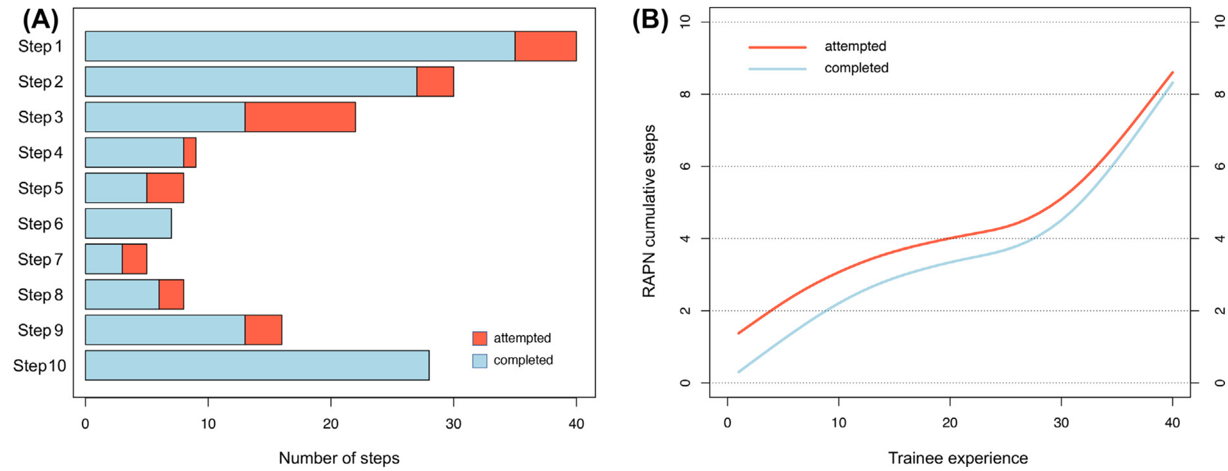

Fig. 2 – (A) Frequencies of individual steps of the European Association of Urology Robotic Urology Section curriculum for robot-assisted partial nephrectomy attempted (red bars) and completed (blue bars). (B) Cumulative number of steps attempted (red line) and completed (blue line) according to increasing trainee experience. Robot-assisted partial nephrectomy steps were defined as discrete segmental units of the surgery in chronological order and consisted of the following steps: (1) trocar placement and specimen retrieval; (2) bowel/liver mobilization; (3) hilum control; (4) Gerota fascia opening; (5) ultrasound scan and tumour demarcation; (6) artery clamping and declamping; (7) tumour excision; (8) inner renorrhaphy; (9) outer renorrhaphy; and (10) Gerota fascia closure. RAPN = robot-assisted partial nephrectomy.

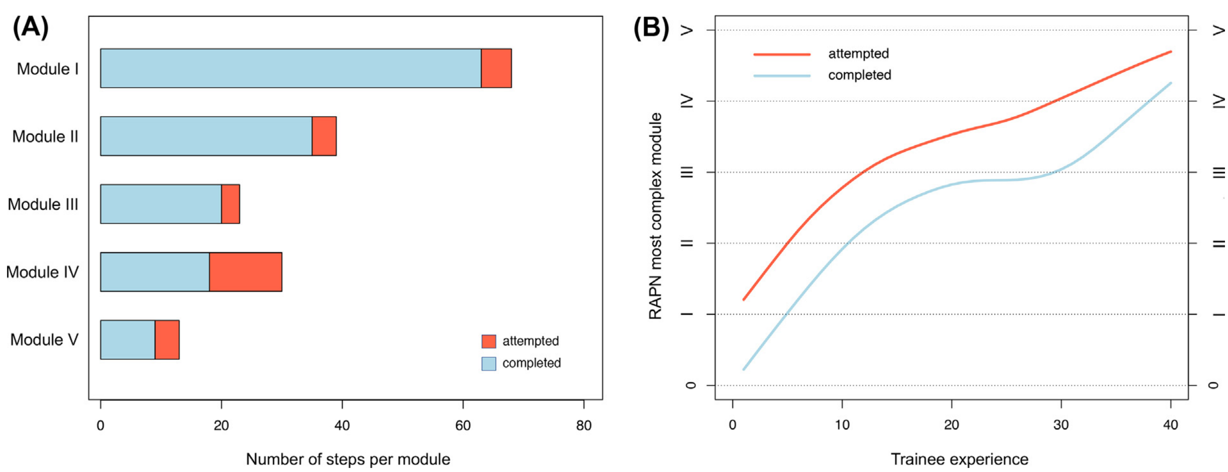

Fig. 3 – (A) Frequencies of steps of the European Association of Urology Robotic Urology Section curriculum for robot-assisted partial nephrectomy attempted (red bars) and completed (blue bars) stratified according to modules of increasing complexity from I (easy) to V (complex). (B) Maximal complexity of module attempted (red line) and completed (blue line) according to increasing trainee experience. Robot-assisted partial nephrectomy modules were defined as unit comprising the steps with same complexity using a scale from I (easy) to V (complex) regardless of chronological order and consisted of the following modules: (I) trocar placement and specimen retrieval and Gerota fascia closure; (II) bowel/liver mobilization and Gerota fascia opening; (III) artery clamping and declamping and outer renorrhaphy; (IV) hilum control and ultrasound scan and tumour demarcation; and (V) tumour excision and inner renorrhaphy. RAPN = robot-assisted partial nephrectomy.

procedure-specific learning process. Conversely, the magnitude of operative time delay recorded when any unstructured training is operational is unknown and, therefore, no valid comparison is possible. However, two contributing factors explain the delay recorded in cRAPN. First, experienced surgeons are faster than unexperienced surgeons due to faster identification of anatomical landmarks, quicker dissection, and less common occurrence of unnecessary manoeuvres. Second, the trainee–trainer interaction between modular training is based on instruction, feedback, discussion, and control switch between dual console, and all these processes are time-consuming.

The efficacy data are in line with previous investigations demonstrating different learning curves according to different level of complexity of each single step in the setting of RARP [10]. Of note, the 17 (173/10) average individual attempts per step recorded in the current study favourably compare with the same figures observed in the setting of RARP where those were 12 (210/17). These data highlight that the longer duration of the current study reflects the relative difference in RARP and RAPN hospital volume and indicate that the latter is not only a determinant of clinical results [32] but also of training capability. In this regard, it is also noteworthy that a minimum annual volume of 40 cases has been identified as eligibility criteria to host the program by the Delphi consensus process.

Finally, in a multifaceted scenario when ethical and legal issues together with economic constraints are relevant concerns in medical practice and can be operational as a barrier to surgical training, the findings of this study are also important with respect to the unmet need for certification and recertification after initial training and can be regarded as a benchmark in the credentialing process [33] for RAPN.

Despite its novelty and strength, the current study is not devoid of limitations, mainly related to its pilot nature. First and foremost, only a single trainee participated in the program and the generalizability of this study must be validated in a larger cohort of curriculum participants. However, given the background of the trainee, no bias related to the confounding effect of previous experience in open, laparoscopic, or robot-assisted renal surgery was operational, and this element represents a major element of robustness that is peculiar to this report only. Similarly, a single institution hosted the program and the generalizability of this study must be validated in a multi-institutional setting. However, the high RAPN annual volume at the selected institution (>50 cases/yr during the study period) qualifies it as the ideal setting to operate the curriculum. Because of the aforementioned characteristics, the number of patients treated in the context of the program was relatively small and, in consequence, the comparative analysis estimating treatment effect yielded relatively wide CIs. Hence, although our results do not support any evidence of clinical detriment for patients included in the curriculum, this study cannot be regarded as a formal noninferiority trial and confirmation on a larger sample is mandatory. It is also important to note that the structure of this study allowed for the construction of a granular data set and for a detailed analysis of clinical and training outcomes that was never performed previously and represents an original and exclusive strength of the current report.

Moreover, the impact of each individual steps and modules on patient's outcome might be different, and, in contrast with previous work depicting step-specific learning curves [10], subanalysis according to individual steps and modules was not possible due to the relatively limited sample size of the cRAPN cohort. Finally, data for the longitudinal analysis of long-term renal function and oncologic outcomes of cRAPN and of the cases independently performed by the trainee after the completion of the program are not mature yet. This limitation prevents a comparative analysis of the learning curve of surgeons trained according to the prosed program relative to nonstandardized training. All the aforementioned caveats represent the objectives of the forthcoming research activity of the ERUS Educational working group and must be regarded as mandatory to validate the proposed program.

Notwithstanding these limitations, this study stands out for its novelty and uniqueness because it describes the first curriculum for RAPN and, for the first time in the setting of robot-assisted surgery, the full process of training curriculum development was completed [9], from learning needs' identification through implementation to clinical outcomes report using a comprehensive comparative analysis.

5. Conclusions

This study is the first definition and clinical validation of a training curriculum for RAPN. The ERUS curriculum for RAPN can protect patients from suboptimal outcome during the learning curve of the surgeons and can aid surgeons willing to start a RAPN program. In the pilot phase of clinical validation, no evidence of any detriment with respect to patient's clinical outcomes was recorded and the program allowed for the transition from the beginning of surgical experience through increasing responsibility to the independent completion of a full case. To ensure generalizability, the observed safety profile must be confirmed in a larger cohort of patients and the observed efficacy profile must be confirmed in a larger cohort of trainees in a multi-institutional setting.

Author contributions: Alessandro Larcher has full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Larcher, Mottrie.
Acquisition of data: Larcher, De Naeyer, Turri, Dell'Oglio, Capitanio, Mottrie.
Analysis and interpretation of data: Larcher, De Naeyer, Turri, Dell'Oglio, Capitanio.
Drafting of the manuscript: Larcher, Turri, Dell'Oglio.
Critical revision of the manuscript for important intellectual content: De Naeyer, Capitanio, Collins, Wiklund, Van Der Poel, Montorsi, Mottrie.
Statistical analysis: Larcher, Turri, Dell'Oglio.
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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at https://doi.org/10.1016/j.eururo.2019.02.031.

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