Complementary routes towards precision urologic surgery: image guidance technologies and standardized training programmes

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PART 2

Acquisition of surgical skills in robotic surgery: the need for standardized training programmes

CHAPTER 6

THE SAFETY OF UROLOGIC ROBOTIC-SURGERY DEPENDS ON THE SKILLS OF THE SURGEON

Based on:

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ABSTRACT

Objective: The aim of the current narrative review was to assess the available literature evidence that discusses the effect of surgical experience on patient outcomes in robotic setting. This information is used to help understand how we can develop a learning process that allows surgeons to maximally improve patient safety. Available surgical training programmes and the importance of non-technical skills were assessed.
Methods: A literature search of the MEDLINE/Pubmed and Scopus database was performed. Original and review articles published in the English-language were included after an interactive peer-review process of the panel.
Results: Robotic surgical procedures require high-level of experience in order to guarantee patient safety. This means that, for some procedures, the learning process might be longer than originally expected. In this context, structured training programmes that assist surgeons to improve outcomes during their learning processes were extensively discussed. We identified few structured robotic curricula and demonstrated that for some procedures curriculum trained surgeons can achieve outcomes rates during their initial learning phases that are at least comparable to those of experienced surgeons from high-volume centres. Lastly, the importance of non-technical skills on patient safety and of their inclusion in robotic training programmes was also assessed.
Conclusions: In order to guarantee safe robotic surgery and to optimize patient outcomes during the learning process, standardized and validated training programmes are instrumental. To date, only few structured validated curricula exist for standardized training and further effort is needed in this direction.

INTRODUCTION

In the United States every year more than 250,000 deaths occur due to medical error, as reported by a recent Johns Hopkins University's study [1]. Medical errors may lead to an estimated overall cost of about 17-29 billion dollars [2]. Combined the social and economic aspects of these errors strongly underline that we should strive to provide a higher quality of care to our patients. However, measures to improve surgical safety are still largely missing or unknown. Improving patient safety represents a growing priority for health professionals and institutions. In 2009, the World Health Organization (WHO) created the safety guidelines for surgery in order to promote standardization of practice, to avoid errors during surgery and to ensure patient safety [3]. In this document, factors responsible for surgical errors were analysed and categorized as follows: high workload, inadequate knowledge, lack of skills or experience, inadequate supervision or education, stressful environment and mental fatigue [3]. Despite the fact that the majority of these factors could potentially be mitigated by adequate training, surgeon training was not mentioned in the aforementioned safety guidelines.

The exponential growth of robot-assisted surgery revolutionized the world of minimally invasive surgery, establishing itself as a new reliable technology in many different specialties [4-6]. However, compared to more traditional open and laparoscopic surgical approaches, robot-assisted surgery brings a specific set of (new) safety features [7-9]. Indeed, between 2000 and 2013 approximately 10,624 adverse events related to robotic procedures were reported in the United States among different surgical specialties [10]. In the light of these data, the European Commission of WHO created the Patient Safety in Robotic Surgery (SAFROS) project [11]. The aim of this project was to explore whether robotic surgery, carried out in accordance with safety criteria, can improve the level of safety currently achievable by traditional surgery. Specifically, it analysed safety in robotic surgery, formalized safety requirements and established safety procedures and verifications protocols [11]. Moreover, since several studies demonstrated the importance of surgical experience on the improvement of patient outcomes [12-15], the attention focused also on adequate training and preparation of robotic surgeons. To achieve standardization of procedures that represents a recognized safety factor for patients, the development of structured robotic surgical training programmes has become a priority [8]. Furthermore, in training, the surgeon should not be considered the sole author of a technical procedure. Rather, successful execution of a surgical procedure should be seen as a team effort; the whole environment of the operating room involves multiple professionals that interface with patients at different levels. Thus, training should not only address the technical skills of the surgeon, but also his/her ability to manage the collaboration between the team of health-care professionals.

The aim of the current review was to isolate key factors that allow a surgeon to perform a safe robot-assisted procedure. Specifically, we focused on the available evidence on the learning phase in urologic robotic setting and how we could assist naïve surgeons to maximally improve patient safety and outcomes during their learning process. Subsequently, the available surgical training programmes and the importance of non-technical skills were assessed.

EVIDENCE ACQUISITION

A literature search of the MEDLINE/Pubmed and Scopus database was performed. The research process was divided into three main topics related to the acquisition of skills: learning curve, robotic training and non-technical skills. For each topic a systematic literature search was performed with subsequent analysis of the results obtained. The search terms used were (*urology* OR *robotic surgery*) AND (*training* OR *simulation* OR *learning curve* OR *skill OR curriculum*) AND (*safety*).

Only English-language original and review articles published between January 2000 and March 2019 were included. The relevant studies selected were analysed and summarized after an interactive peer-review process of the panel.

DISCUSSION

Technical learning curve

A learning curve is a graphical representation of the concept of the improvement of surgical outcomes with the increasing of surgical experience [16]. The surgical outcomes that are generally assessed in a learning curve are related to technical aspects (i.e: operative time, transfusion rate), complications, oncological and/or functional results [17,18]. Theoretically, the performance of a training naïve/novice surgeon is expected to improve over time – in line with the learning curve- with each surgical procedure. Therefore, the learning curve is characterized by an initial learning phase, where the outcomes are significantly affected by the surgical experience, and by a subsequent plateau phase, where the impact of surgical experience becomes marginal.

However, given the complexity of some surgical procedures, it may take substantially longer to reach the plateau phase, especially for stronger outcomes such as severe complications or oncological outcomes.

Several studies attempted to evaluate the relationship between surgeon experience and patient outcomes in different urologic robotic procedures [10,14, 19-27] (Table 1). Unfortunately, instead of assessing the learning process as the number of prior robotic surgeries performed by the surgeon at the time of the index patient's operation [16], the majority of these studies divided the patient population into different categories [14, 20, 28, 29]. This has been demonstrated to draw unwarranted conclusions [30], underestimating the number of the procedures needed to reach the potential plateau of the learning curve [31]. For instance, in the setting of robot-assisted radical prostatectomy (RARP), the number of robotic procedures for a novice surgeon/naïve laparoscopic surgeon needed to stabilize the operative time varied between 30 and 250 [21,23-26], while the number of procedures needed to master urethra-vesical anastomosis was 10 [23]. Moreover, the number of surgeries needed to significantly reduce the overall rate of postoperative complications varied between 30 and 175 among different studies [20,22,25]. The wide ranges of these data may be related to the lack of standardized statistical methodology that analyse expertise in a continuous fashion accounting for potential non-linear relationship between outcomes and experience progression. Therefore, these results should be interpreted with caution.

Several studies on RARP learning curve are also limited by the fact that they exclusively focused on technical aspects without assessing the learning process on cancer control, that is mandatory considering the reason for which the patients undergo surgery. On this direction, few reports assessed the impact of surgeon experience on oncologic efficacy of RARP [13,28,32,33]. It merits mention the study by Bravi et al. [32] that relied on a large cohort of prostate cancer (PCa) patients (n=2,231) treated with RARP at a single tertiary care referral centre by nine surgeons. The authors observed a significant, non-linear relationship between surgeon experience and positive surgical margins (PSMs), with a steep reduction after 200th procedure. However, the authors failed to observe a relationship between surgical experience and biochemical recurrence (BCR). Contrarily to what commonly believed, these data could suggest that the high dexterity of robotic surgery might guarantee optimal cancer removal also in less experienced hands. Moreover, it is of note that previous experience in open surgery was not associated with the risk of PSMs during RARP [32], emphasizing that there is a learning curve in RARP also for expert open surgeons. In the same direction, Thompson et al. [13,33] analysed whether high-volume experienced open surgeons can improve their functional and oncological outcomes with RARP. Specifically, for a single surgeon who performed more than 3,000 open RP they reported that the risk of PSMs for RARP relative to open RP became lower after 382 cases, plateauing after 484 cases. The authors [13,33] reported for the first time that the improved PSMs rate for RARP resulted in improved biochemical control. The risk of BCR of RARP vs. open RP rapidly decreased with the increasing number of procedures performed, and became lower after 191 cases, plateauing after 226 cases. Similar findings were observed when functional outcomes were investigated. Mean RARP sexual function and sexual bother scores surpassed open RP scores after approximately 160 procedures. Moreover, after almost 140 procedures the adoption of robotic technology resulted into a better early urinary function and incontinence domains. More than 400 procedures were needed to allow that RARP yielded a superior performance than open RP for late urinary function and incontinence scores [13,33]. All these findings indirectly suggest that to improve the learning process of RARP, a structured robotic training is mandatory also in skilled open surgeons. Indeed, evidence confirms that fellowship-trained robotic surgeons outperform earlier experienced open RP surgeons incorporating RARP into practice, with regards to perioperative morbidity and oncological outcomes [34].

Table 1: *Learning curve studies on robot-assisted urological procedures*

Study	No. of patients	No. of surgeons	Previous surgical experience	Operation	Outcomes	No. of cases needed to observe an improvement and a plateau phase in the outcomes measured
Di Pierro et al. 2014 [20]	233	2	Open + laparoscopic	RARP	Complication	175
Sivaraman et al. 2017 [28]	5547: (1701 RARP)	9	---	RARP	PSM, BCR	PSM, BCR: 100
Ou et al 2011 [29]	200	1	---	RARP	OT, BL, BT, Complications	OT: significant improvement, plateau not reached BL-BT: 50 Complications: 150
Gumus et al 2011 [26]	120	1	Open	RARP	OT, LOS, PSM, BL, EC, potency	80-120 for all the outcomes
Monnerat et al 2018 [21]	133	1	Laparoscopic	RARP	PSM, OT, potency, EC	OT, potency, EC: 100 PSM: plateau not reached
Sharma et al. 2010 [24]	500	2	Open + laparoscopic	RARP	OT, BL, PSM, EC, potency	OT, BL: significant improvement, plateau not reached EC, potency: 100 PSM: 450
Giberti et al 2010 [25]	200		---	RARP	OT, PSM, EC, potency, Complications	OT, Complications, potency, EC: 100 PSM: 200
O'Malley et al. 2006 [23]	110	2	Open	RARP	OT, PSM, VUAT	OT:40 VUAT:10 PSM: 200
Bravi et al. 2019 [32]	2857	9	Open	RARP	PSM, BCR	PSM>200* BCR: no significant improvement, plateau not reached
Thompson et al 2014 [33]	1520	1	Open	RARP	PSM, SF, SB, EC, UB, UF	PSM: T2: 108, >400-500*; T3-4 >200-300* SF: 99 >600-700* SB: 123 >300-400* EC: 182 >700-800* UF: 144 >300-400* UB: 58 >300-400*
Thompson et al 2017 [13]	1520	1	Open	RARP	PSM, BCR, SF, SB, EC, UF, UB	PSM: 382 >484* BCR: 191 >226* SF: 139 >405* SB: 191 >330* EC: 124 >365* UF: 151 >659* UB: 47 >360*

Table 1 *(continue)*

Study	**No. of patients**	**No. of surgeons**	**Previous surgical experience**	**Operation**	**Outcomes**	**No. of cases needed to observe an improvement and a plateau phase in the outcomes measured**
Mottrie et al 2010 [35]	62	1	Robotic	RAPN	WIT, OT, BL, complications	Short learning curve for all the outcomes
Dias et al 2018 [36]	108	1	Laparoscopic	RAPN	WIT, OT, BL, trifecta	WIT>44* OT>44* BL>54* Trifecta>44*
Xie et al 2016 [37]	144	1	Laparoscopic	RAPN	MIC	90
Hanzly et al 2015 [39]	116	1	Laparoscopic + Robotic	RAPN	OT, WIT	OT: 150 WIT: 30
Larcher et al 2019 [49]	457		Robotic	RAPN	WIT, complications, PSM	WIT: 150 Complications: significant improvement, plateau not reached PSM: no significant improvement, plateau not reached
Paulucci et al 2017 [40]	960	4	Laparoscopic, open, robotic	RAPN	WIT, BL, BT, LOS, trifecta	300: significant improvement for all the outcomes, plateau not reached
Collins et al [14]	67	2	Robotic	RARC + intracorporal neobladder	OT, LOS, LNY	OT:10 LOS: no significant improvement LNY: no significant improvement
Richards et al 2011 [41]	60	1	Robotic	RARC	OT, BL, LOS, LNY, complication	OT, BL, LOS, complication: 20-40 LNY: plateau not reached
Hayn et al 2010 [27]	496	21	---	RARC + extracorporeal urinary diversion	OT, LNY, PSM, BL, LOS,	OT: 21 LNY, BL: 30 LOS: plateau not reached PSM: 30 (not significant)

OT: operative time; BL: blood loss; PSM: positive surgical margins; EC: early continence; BT: blood transfusion; LOS: length of stay; VUAT: vesico-urethral anastomosis time; SF: sexual function; SB: sexual bother; UR: urinary continence; UB: urinary bother; WIT: warm ischemia time; LNY: lymph node yield; MIC: margin-ischemia-complications. *: plateau phase of the learning curve.

Regarding the robot-assisted partial nephrectomy (RAPN) setting, the majority of the studies that assess the learning process of this minimally invasive procedure are limited by their sample size (Table 1) [35-38]. This limits the ability to accurately assess the learning-curve. Larcher et al. [39], however, reported the learning curve for RAPN based on a multi-institutional cohort of 457 consecutive patients diagnosed with cT1-cT2 renal mass. In this study, a significant, non-linear relationship between surgical experience and optimal warm ischemia time was observed after accounting for different confounders, yielding a plateau after 150 procedures. A significant relationship was also identified between surgeon experience and Clavien-Dindo ≥2 complications-free course, suggesting that surgical expertise is mandatory to reduce the risk of postoperative complications in RAPN setting. As this relationship is linear [39], it suggests that the learning process with respect to postoperative complications is continuously evolving and is longer than expected. In this context, the study by Paulucci et al. [40] should also be mentioned. This study underlined that perioperative outcomes (i.e. warm ischemia, estimated blood loss, blood transfusion, length of stay and trifecta achievement) continue to improve up to 300 procedures, despite an increase over time in patient morbidity and tumour size. These RAPN-related findings overwhelmingly underline that the learning curve for RAPN is long and complex and skilled surgeons are needed to safely perform this procedure.

Regarding robot-assisted radical cystectomy (RARC), only few studies assessed the relationship between surgeon experience and patient outcomes after RARC (Table 1) [14,27,41]. For example, Hayn et al. [27] reported the largest series (n=496) evaluating the learning curve for RARC with the majority of patients undergoing extracorporeal urinary diversion by 21 surgeons, with different previous experience in robotic surgery (7 surgeons performed less than 50 RARP, 5 performed between 50-100 RARPs, 3 performed between 101-150 RARP and 6 performed more than 150 RARPs). The authors reported a relatively low number of minimum required procedures for a stabilization of the defined outcomes. Specifically, they observed an optimal operative time of 390 minutes after reaching a plateau at 21 cases. Moreover, 30 cases were needed to obtain a count of 20 lymph nodes removed and to have a 5% overall PSMs rate [27]. To date, only one study assessed the learning curve for RARC with intracorporeal neobladder in 67 patients treated by two surgeons [14]. An early decreased of operative time, overall complications and length of stay was observed.

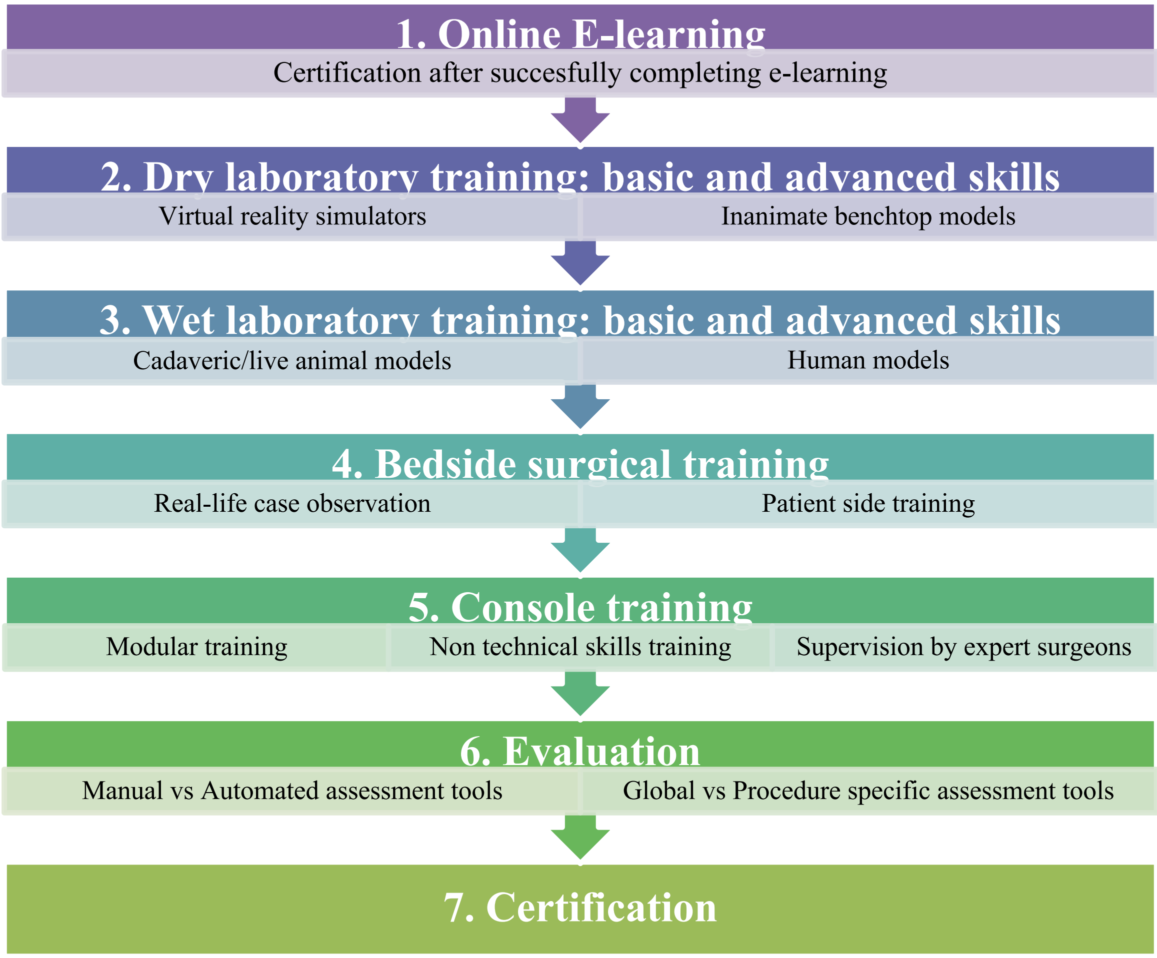
Conversely, blood loss, lymph node yield and PSMs rate could not be related to the experience of the surgeon [14]. Unfortunately, none of these analyses used appropriate statistical adjustment methods that accounted for the impact of inter-surgeon variability and previous robotic/open experience [16]. Therefore, the likely short RARC learning curve provided by the aforementioned studies may be related to the different surgical experience developed before RARC learning process was started. Moreover, the aforementioned studies were also limited by their historical nature [14,27,41] and small sample sizes [14,41]. Thus, further analyses using clustering methodology at surgeon level in contemporary RARC series are urgently needed.

To summarize, robotic surgery continues to be challenging and not devoid of complications. To improve patient safety and outcomes, surgical expertise is mandatory especially for stronger outcomes [13,33,42]. This calls for structured, validated training programmes that represent the ideal starting point for surgeons to reduce the length of their learning process [31,43, 44].

Robotic Surgical Training

Robot-assisted surgery has created new challenges in terms of training and teaching. Robotic surgery comes with specific difficulties since the platform is very different from other forms of surgery [5,7-9]. Although seen as an evolution of laparoscopic surgery, the skills needed in robotic surgery are unique and cannot be compared to those needed in laparoscopic or open surgery. In robotic surgery, the required skills are mainly for console control, manoeuvres without haptic feedback and communication with the bedside assistant. Conversely, in laparoscopic surgery, the required skills are mainly for 2D surgery with instruments with a restricted range of motion. The guidelines that exist for training in laparoscopic surgery therefore cannot be considered an equivalent to robotic surgery and new, specific and structured educational curricula for robotic surgery are needed [8]. Robotic surgery training curricula increase preclinical exposure avoiding patients to be used as a training module, which is unacceptable from an ethical point of view. The validation of these structured curricula will help standardization of training in robotic surgery with accreditation and certification of surgeons for robot-assisted surgery.

A robotic training curriculum should follow precise and well-defined steps [5]:



Specifically, a training curriculum should start with adequate theoretical knowledge development (i.e. *e-learning*). It can be accessed using web-links and it involves three different teaching modules: transmission of theoretical knowledge, teaching on surgical techniques and instructions on virtual patients. A trainee should become familiar with the robotic technology by education on the specific robotic device's parameters and functions. Knowledge and workings of the console is of the utmost importance. Instructions on troubleshooting and the limitations of the operating system are essential. Online modules are available that introduce the basic concepts of the only commercially available system, the Da Vinci Robot (https://www.davincisurgerycommunity.com/Training?tab1=TR). Such an approach allows for a first acquaintance with important information for robot-assisted surgery and it is characterized by flexibility, ease of access and ease of updating [45]. Certification in these online modules is essential before starting any console training. After a trainee is well educated on the robotic platform, the training of robotic technical skills can start.

The first step consists in performing *dry laboratory exercises* on inanimate bench-top models or virtual reality simulated environments. These exercises are an important step in achieving basic and advanced console skills and improving coordination development, bimanuality, dissection and suturing techniques. Simulators are cheap to run, well tolerated, convenient and efficient. However, the exercises that we can perform with virtual reality simulators lack bleeding and do not compare with real life surgery. The *wet laboratory* should be the next step in training after basic surgical skills are acquired in the dry laboratory. In the wet laboratory surgical techniques are trained on cadaveric (i.e. dog model) or live animals (i.e. porcine model) or human cadavers. These anatomical models are more comparable to real life surgery, allowing the trainees to learn to recognize the robustness and consistency of real tissues, to simulate complete surgical procedures and emergency scenario such as vascular/organ injuries. Subsequently, *real-life case observation* in a training centre is essential. This should include *patient side training* with learning of basic surgical skills such as patient positioning, establishing pneumoperitoneum, procedure specific port placement, robot docking and basic laparoscopic skills. Only after going through all these steps, a trainee can start performing *supervised surgery in a modular fashion* under the supervision of expert surgeons. The learning curriculum ends with independent performance of surgery. The curricula must include a *final evaluation* that allows to verify the learning of the procedure. Only after positive evaluation, the trainee should be *certified* as a robotic surgeon.

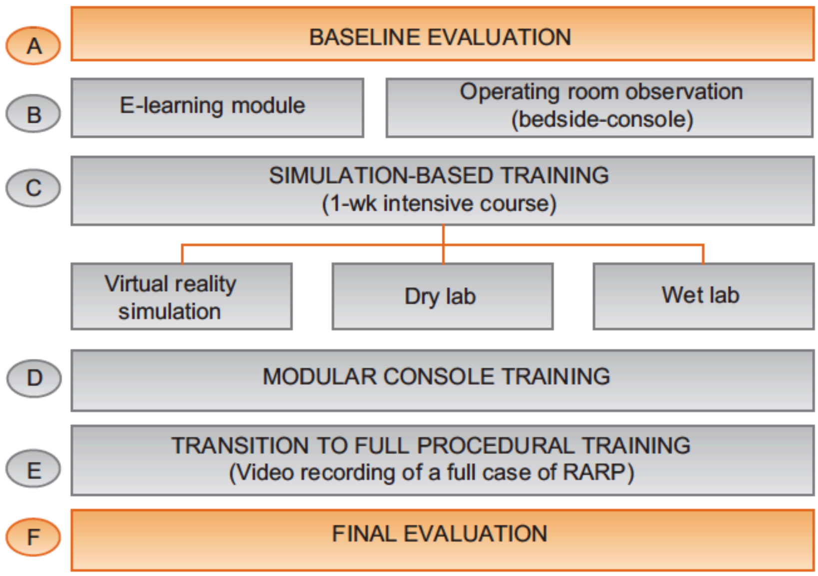
The European Association of Urology Robotic Urology Section (ERUS) developed the first structured and validated curriculum in urology that specifically focuses on RARP (Table 2) [43]. The **ERUS robotic surgery training curriculum** is a 12-week comprehensive training course which was developed based on an expert panel discussion in 2015. After undergoing a specifically developed e-learning module (Figure 1), the trainees observe and assist during live surgery for three weeks. This is followed by an intensive week of structured simulation-based training that includes virtual reality simulation (using the da Vinci Skills Simulator), dry laboratory (synthetic model) and wet laboratory simulation platforms (deceased animals [canine model] and live animals

Table 2: *Basic training and urologic robotic surgery curricula*

Name	Study	Year	Validation	Field
ERUS robotic surgery training curriculum	Volpe, et al. [43-44]	2014	VALIDATED	Urology
British Association of Urological Surgeons (BAUS) Robotic surgery curriculum	Not published [58]	2015	NOT VALIDATED	Urology
The ERUS Curriculum for Robot-assisted Partial Nephrectomy	Larcher et al. [56]	2019	VALIDATED	Urology
The ERUS Curriculum for robot-assisted radical cystectomy	Dell'Oglio et al. [57]	2019	NOT VALIDATED	Urology
Fundamental skills of robotic surgery (FSRS)	Stegemann AP, et al. [59]	2013	VALIDATED	Basic training
Proficiency-based robotic curriculum	Dulan G, et al. [60]	2012	VALIDATED	Basic training
University of Toronto Basic skills training curriculum (BSTC)	Foell K, et al. [61]	2013	VALIDATED	Basic training
Fundamentals of robotic surgery: Orlando group	Macgregor JM et al. [64]	2012	NOT VALIDATED	Basic training
Texas Association of Surgical Skills Laboratories (TASSL) Training collaborative	Lyons C, et al. [65]	2013	NOT VALIDATED	Basic training
Roswell Park Cancer Institute Robot Assisted Surgical Training (RAST) program	Attalla K, et al. [63]	2013	NOT VALIDATED	Basic training
Fundamentals of robotic surgery (FRS)	Smith R, et al. [66]	2014	NOT VALIDATED	Basic training
Fellowship of International College of Robotic Surgeons (FICRS)	Not published [62,64]	NA	NOT VALIDATED	Basic training

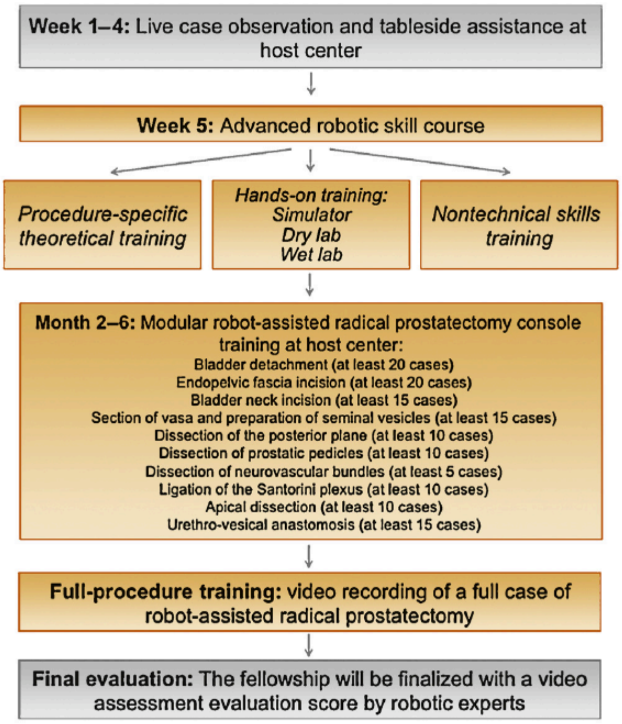
[porcine model]). The technical robotic skills included in the virtual reality simulation are EndoWrist manipulation, camera movement and clutching, use of energy and dissection and needle driving [46]. From an ethical point of view, it is best to learn these technical characteristics through the use of virtual simulators [5,8,47,48], that allow to replicate the steps of different urologic procedures. Recent evidence suggests that this preclinical simulation-based phase significantly improves surgical performance as measured using objective metrics [49]. During this intensive week of structured simulation-based training, improvement of technical skills is assessed by comparing the scores at baseline and on final assessment, using the inbuilt validated assessment metrics on the da Vinci Skills Simulator. After 1-week simulation-based training, the trainees move on the 8-week clinical modular training on RARP under expert surgeon supervision. This module involves progressive, proficiency-based [50,51] training through surgical steps with increasing levels of complexity [43,44]. At the end of the clinical training, the surgeon must perform and record a complete procedure that will be blindly evaluated by an external committee using a validated score that is assigned through recognized assessment tools, like the Global Evaluative Assessment of Robotic Skills (GEARS) score [52].

Figure 1*: Structure of the European Association of Urology Robotic Training Curriculum [43]*



Volpe et al. [43] assessed the validity of the ERUS training curriculum enrolling ten international fellows in the training program. All trainees completed the e-learning module and passed the final test for the assessment of theoretical knowledge successfully. Afterwards, the trainees observed and witnessed a minimum number of procedures (> 12 cases) during the first three weeks of the curriculum. The trainees then followed an intensive week of laboratory training, after which their overall score for da Vinci Skills Simulator tasks significantly increased. In the next 8 weeks, trainees started with supervised modular training, in which they were involved as surgeons in, on average, 18 operations. After completing the curriculum, 80% of trainees was deemed able by their expert supervisors to perform a RARP independently, effectively and safely. Volpe et al. [43] proved that the structured 3-month ERUS training curriculum is feasible, acceptable and effective in improving the robotic technical skills and abilities of young surgeons with limited previous robotic experience to perform the surgical steps of RARP. After its initial publication in 2015 [43], the curriculum was recently updated by doubling the training periods from three to six months, so that even the most inexperienced participants are confident to continue and finish the training with the awareness of having the time to improve [44] (Figure 2).

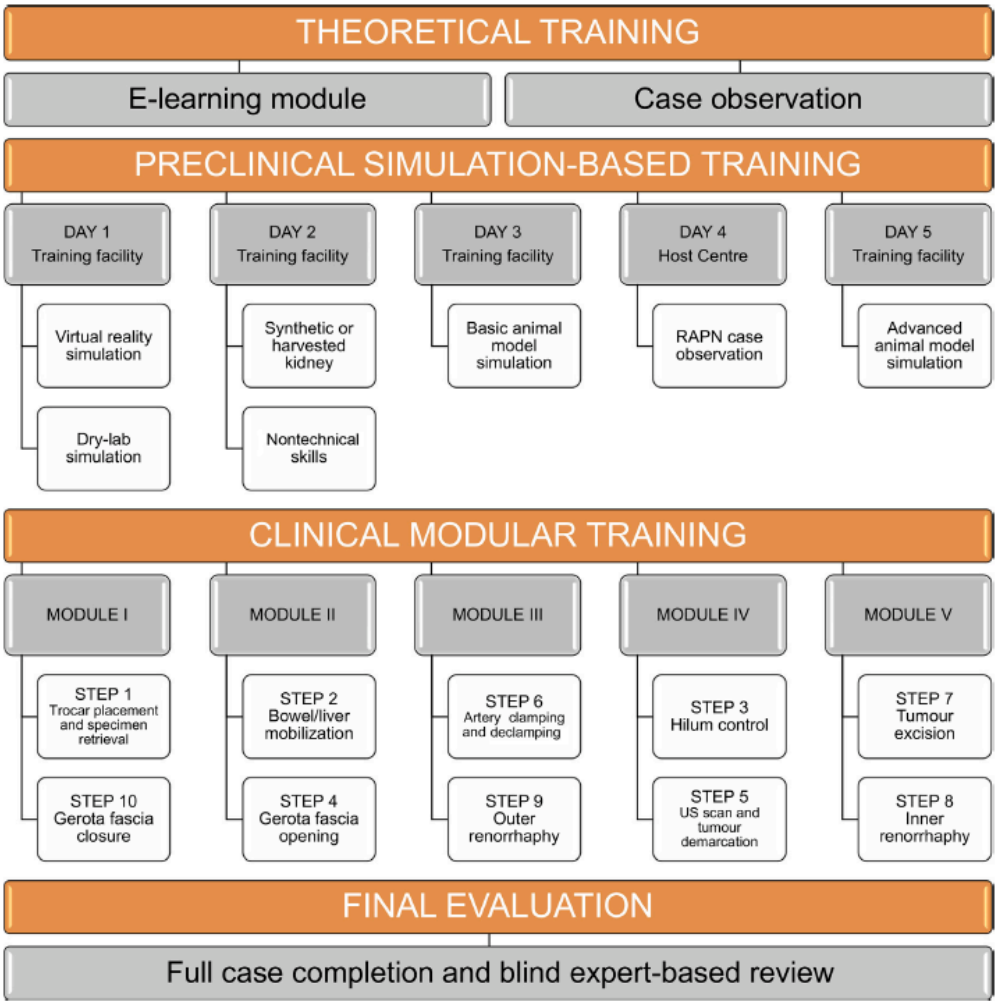
Figure 2: *Structure of the European Association of Urology Robotic Training Curriculum Updated [44]*



Recent studies reported the effect of structured RARP training on outcomes [53-55]. Schiavina et al. [54] demonstrated that optimal perioperative and functional outcomes may be attained in an early phase of the learning curve after an intensive structured modular training, with less than 100 consecutive procedures needed to achieve optimal urinary continence and erectile function recovery. Similarly, Bedir et al. [55] showed that a RARP curriculum trained surgeon may achieve high outcome rates in his initial learning phase, that are comparable to those of experienced surgeons from high-volume referral centres.

Recently, a new **training program on RAPN** was presented by the ERUS with the aim of helping surgeons willing to start robotic renal cancer surgery [56] (Table 2; Figure 3).

Figure 3: *Structure of the ERUS Curriculum for Robot-assisted Partial Nephrectomy [56]*

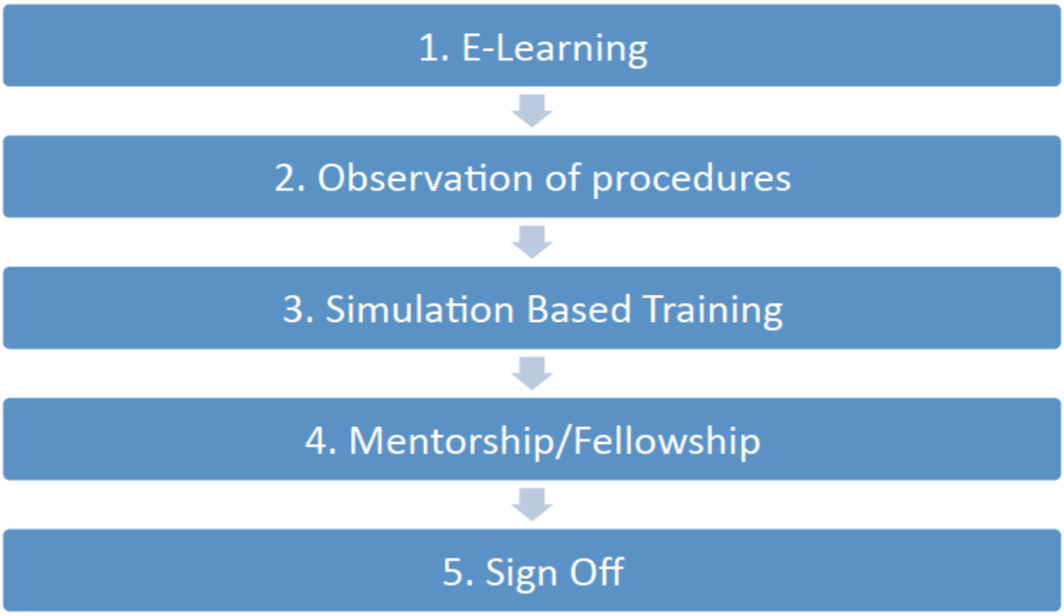


Similar to the RARP curriculum course, this RAPN-specific pathway guides the trainee from theoretical knowledge to preclinical learning, passing through virtual reality simulators, dry and wet laboratory training, up to clinical-based modules practice. After the initial e-learning phase, the RAPN course starts with an intensive week of preclinical simulation-based training that closely replicate that of RARP curriculum course. Subsequently, the course proceeds with a clinical modular training that is based on the partition of a complete RAPN case into 10 fundamental steps, according to the chronological order of each unit, and into modules according to the complexity of each unit [56]. Specifically, five modules including ten specific steps were proposed and ordered according to the increasing level of step complexity after a Delphi consensus process by a panel of experts in the field of RAPN. The progression of the trainee through more complex modules is allowed only when the less complex ones are completed. A pilot clinical validation of this RAPN curriculum was performed. The trainee, without previous experience as first-hand in open, laparoscopic of robot-assisted major urological surgery, completed all phases of the curriculum without a detrimental effect on patient's outcomes in terms of perioperative morbidity, early renal function or pathologic outcomes. Moreover, the trainee's experience was associated with higher number of steps attempted and completed and with increasing maximal complexity of module attempted and completed [56]. Therefore, the ERUS curriculum for RAPN is safe and can guide a naïve surgeon during their learning curve and protect patients from suboptimal outcomes during the learning process.

Subsequently, the first structured **training curriculum for RARC** led by ERUS educational board based on simulation activity, clinical training and non-technical skills aimed at improvement of patient safety and outcomes during RARC learning process, was developed [57] (Table 2). However, clinical implementation of this curriculum is still missing and, in consequence, urgently needed.

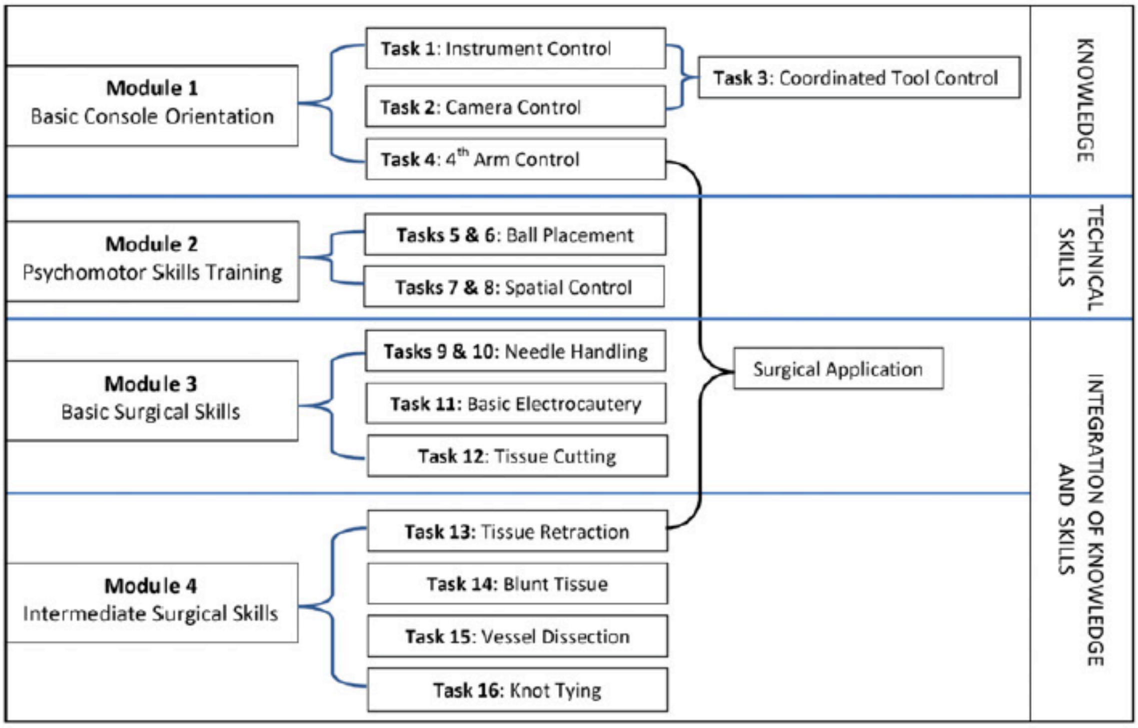
The **British Association of Urological Surgeons (BAUS) curriculum** (Table 2) [58] represents another non-validated training model in urological field. It is largely based on the ERUS curriculum [43,44], with five recognized stages: online theoretical training/e-learning, observation of procedure, simulation-based training, a mentorship/fellowship period, and sign-off for independent surgery (Figure 4). The modular training approach of the BAUS curriculum is applicable to upper tract and pelvic urological procedures, namely RARP, RAPN, robot-assisted radical nephrectomy, RARC and robot-assisted pyeloplasty. For each procedure, there are suggested numbers of cases and also procedure-specific quality indicators [58].

Figure 4: *Outline of BAUS curriculum [58]*



Expanding research outside the urologic field, several basic robotic surgical curricula have been created. For example, the **Fundamental Skills of Robotic Surgery (FSRS) training curriculum** [59] is a validated, structured, simulation-based training program that was created by the Roswell Cancer Institute in Buffalo, USA (Table 2). The curriculum consists of 4 modules (orientation, motor skills, basic, and intermediate surgical skills) with a series of 16 tasks, each task containing 3 difficulty levels and an evaluation phase (Figure 5). The curriculum is performed on Robotic surgical simulator (RoSS) that automatically records and saves performance metrics of trainees. The tasks were specifically created by a group of expert robotic surgeons with integration of previously validated tasks from the Fundamentals of Laparoscopic Surgery (FLS) curriculum. FSRS curriculum is a valid and feasible training curriculum that can improve trainees' basic robotic surgical skills.

Figure 5: *the Fundamental Skills of Robotic Surgery (FSRS) training curriculum [59]*



Another validated, multidisciplinary robotic curriculum was created by the University of Texas Southwestern Medical Center: the **proficiency-based robotic curriculum** [60]. This validated curriculum is divided in 3 main components: an online tutorial (created by Intuitive Surgical) covering fundamental aspects of robotic surgery, a half-day interactive session and hands-on practice with 9 inanimate exercises (Figure 6, Table 3). The exercises are performed on a standard da Vinci system with box trainer and show increasing degrees of complexity to facilitate proficiency-based skill acquisition. The program lasts two months and trainees have to self-practice the 9 exercises. Finally, they receive an evaluation using FLS metrics.

Figure 6: *The proficiency-based robotic curriculum [60]*

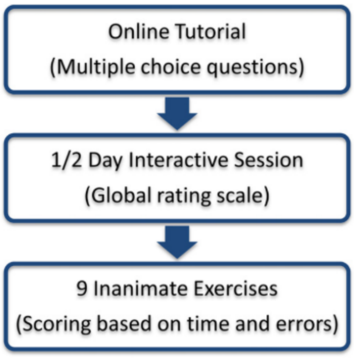


Table 3: *List of 9 inanimate tasks of the proficiency-based robotic curriculum [60]*

Exercise number	Task description
1	Peg transfer
2	Clutch and camera movement
3	Rubber band transfer
4	Simple suture
5	Clutch and camera peg transfer
6	Stair rubber band transfer
7	Running and cutting rubber band
8	Pattern cut
9	Running suture

Moreover, the University of Toronto developed the **basic skills training curriculum (BSTC)**, a validated 4-week training program [61] (Table 2). The first part of training is characterised by didactic lectures and self-directed online training modules (including Fundamentals of Robotic Surgery) before being introduced to the da Vinci robot. The theoretical module, includes: advantages and disadvantages of robotic technology, analysis of the various robotic systems and its equipment, introduction to the patient cart, surgeon console and vision cart, review of the robot installation principles, placement of trocars, docking, exchange of tools, grafting and resolution of common technical problems, several practical training sessions. After the theoretical module, a 2-hour hands-on robotic training session starts, focusing on the topics dealt with the theoretical module. Thereafter, trainees start exercising basic skills on the da Vinci Surgical Simulator such as endowrist manipulation and camera navigation, instrument clutching, instrument and third-arm functionality, object manipulation, needle guidance, suturing and binding of the nodes, cauterization and dissection. This standard set of exercises is repeated for three individual 1-hour sessions on the simulator organized at weekly intervals. The robotic surgical skills of the trainees are evaluated by the built-in assessment tool of the simulator. A trainee passes the test when at least 80% of success has been achieved. Wet lab or real-life surgery training is not included in this training curriculum.

Finally, other non-validated basic robotic surgical curricula are reported in Table 2 [62-66].

One of the points of discussion in validated curriculum is the distribution of the training sessions. Indeed, data from other surgical specialty demonstrated that spacing training sessions improves long-term surgical skills retention when compared to intensive practice [67]. However, data specifically focused on the differential effect of distributed training session in urological robotic surgery are missing. As such, this conclusion may not be applicable to our analysis, suggesting that further efforts are needed to validate these findings in robotic setting.

Finally, it is crucial to define whether the proficiency level of a trainee is reached. To achieve this goal, it is fundamental to define proficiency metrics by four stages: 1) task analysis and metric identification; 2) operational definition of metrics; 3) metric definition verification and refinement; 4) metric validation (relying, for example, on the Delphi methodology [10]). Subsequently, after defining these metrics, it is important to progressively verify knowledge acquisition, psychomotor skill acquisition and, ultimately, to supervise real-world application of the acquired skills [50,51]. This stepwise process defines the proficiency-based progression (PBP) training module. Indeed, it has been demonstrated in prospective, randomized and blinded studies that metric-based PBP simulation training derived from and benchmarked on experienced and proficient surgeons, produces a superior surgical skill-set in comparison to traditional approaches to training [68-73], with an additional potential effect on shortening the learning curve process [74].

Moreover, objective surgical skill assessment has gained interest not only for the evaluation of surgeon proficiency but also for its impact on patient outcomes. For example, Hung et al [75] used automated performance metrics and deep-learning models to predict continence recovery after RARP. The association of kinematic data with clinical patient features showed the highest accuracy in prediction of continence recovery after RARP compared to clinical features only. Furthermore, the patients operated by surgeons with more efficient automated performance metrics had higher continence rate at 3 and 6 months compared to patients operated by surgeons with less efficient metrics [75].

It is also of note that the standardization process of training should not only record metrics of trainees' performances, but it should also be focused on trainers' outcomes in order to guarantee high-level training models. In this context, it has been recently proposed, in a Delphi process-derived consensus of expert opinions, to define the key elements of the "train-the-trainer" program with the intent of providing a structured methodology also for trainers [10]. As such, the standardization process of training has still to be considered as "ongoing". Taken together, these results provide further evidence of the importance of structured training programmes for technical skills improvement and, in consequence, patients safety assurance.

Non-technical skills

What also define experienced surgeons are their non-technical skills that are categorized into cognitive and social skills [76]. The greater technical complexity of robotic surgical procedures requires adequate development of cognitive abilities (situational awareness, decision-making and planning) and social skills that include communication, teamwork and leadership skills [76]. The importance of non-technical skills is increasingly growing [10] especially in minimally invasive surgery considering the fact that surgeons sit behind the console, isolated from the patient and operating room staff. These aforementioned non-technical skills may be objectively evaluated using several validated tools [77], such as the Non-Technical Skills for Surgeons (NOTSS) [78] and the Observational Teamwork Assessment for Surgery (OTAS) [79]. However, it is important to remark that these tools were not developed on robotic surgery and, in consequence, they may not perfectly applied to robot-assisted surgery. In consequence, further research focusing on structured validation of these tools for robotic surgery or de novo development of new robotic-specific assessment tools is required. To date, the Interpersonal and Cognitive Assessment for Robotic Surgery (ICARS) is the only objective non-technical skill assessment tool specifically designed for robotic surgery [80]. Relying on Delphi consensus-based panel of experts, it identifies 28 key non-technical skills that should characterize a robotic surgeon. Overall, the validation analysis demonstrated that the ICARS is able to accurately differentiate between novice, intermediate and expert participants, showing high level of agreement with the NOTSS. Amongst the identified key non-technical skills, the communicative skills are included in one of the major domains of the ICARS. Specifically, effective verbal communication whilst at the console, appropriate communication with bed-side assistant, anaesthetist and theatre staff and ability to engage in confirmatory feedback with theatre staff, are critical abilities for maintaining adequate and safe robotic surgical performance [80].

Indeed, evidence exists that communication failure between hospital staff is one of the leading cause of errors and inadvertent patient harms [5,44,81-85]. For instance, patients had increased odds of complications or death when the following behaviours were exhibited less frequently: information sharing during intraoperative phases, briefing during handoff phases, and information sharing during handoff phases [86]. On the other, a surgeon with well-trained non-surgical skills is able to recognize and manage those situations, such as active venous/arterial bleeding or bowel perforations, that are dangerous for patient's health [87]. In consequence, these tools are mandatory to develop, especially in minimally invasive surgery and must be an integral part of robotic training curricula, with the possibility to learn through a simulation training that can replicate common and emergency scenarios in robotic surgery [76,83,84].

Specific training programmes have been developed in order to provide a standardized model for non-technical skills development [83]. The two main methods used are the classroom lessons and the simulation centres. Classroom lessons can provide an insight to the key components of these skills. Moreover, videos can be analysed and commented on how to change attitudes and lead to self-reflection [88]. Conversely, the simulations allow using models that closely replicate the real-life setting. In this context, bench or virtual reality models are positioned within a simulated or real operating environment and the whole team can participate [89]. By creating a realistic environment, it is possible to develop technical and non-technical skills that allow a complete training and an effective way of debriefing [77,90]. It is useful that an expert surgeon also participates to these simulations in order to create an open discussion and to encourage self-reflection of the trainee. Additionally, the entire operatory room team must be trained in non-technical skills to improve patient safety [91]. Thus, considering the general environment of the operating room, specific training courses should be supported for all team members present during a robot-assisted surgery. Future studies are needed to assess the effect of these training modules on non-technical skills improvement.

CONCLUSIONS

Robotic surgery allows surgeons to perform complex procedures with improved precision, visualization and enhanced dexterity relative to conventional open and laparoscopic surgery. That said robotic surgery is challenging and requires technical and non-technical expertise in order to improve patient safety and outcomes. To be sure a baseline expertise level is met, it is becoming increasingly important to develop standardized and validated training programmes that assist the surgeons during their learning process. To date, only few structured validated curricula exist for standardized training and further effort is needed in this direction.

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