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Development and validation of surgical training tool: cystectomy assessment and surgical evaluation (CASE) for robot-assisted radical cystectomy for men

Ahmed A. Hussein[1,2] · Kevin J. Sexton[1] · Paul R. May[1] · Maxwell V. Meng[3] · Abolfazl Hosseini[4] · Daniel D. Eun[5] · Siamak Daneshmand[6] · Bernard H. Bochner[7] · James O. Peabody[8] · Ronney Abaza[9] · Eila C. Skinner[10] · Richard E. Hautmann[11] · Khurshid A. Guru[1]

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Abstract

Background We aimed to develop a structured scoring tool: cystectomy assessment and surgical evaluation (CASE) that objectively measures and quantifies performance during robot-assisted radical cystectomy (RARC) for men.

Methods A multinational 10-surgeon expert panel collaborated towards development and validation of CASE. The critical steps of RARC in men were deconstructed into nine key domains, each assessed by five anchors. Content validation was done utilizing the Delphi methodology. Each anchor was assessed in terms of context, score concordance, and clarity. The content validity index (CVI) was calculated for each aspect. A CVI ≥ 0.75 represented consensus, and this statement was removed from the next round. This process was repeated until consensus was achieved for all statements. CASE was used to assess de-identified videos of RARC to determine reliability and construct validity. Linearly weighted percent agreement was used to assess inter-rater reliability (IRR). A logit model for odds ratio (OR) was used to assess construct validation.

Results The expert panel reached consensus on CASE after four rounds. The final eight domains of the CASE included: pelvic lymph node dissection, development of the peri-ureteral space, lateral pelvic space, anterior rectal space, control of the vascular pedicle, anterior vesical space, control of the dorsal venous complex, and apical dissection. IRR > 0.6 was achieved for all eight domains. Experts outperformed trainees across all domains.

Conclusion We developed and validated a reliable structured, procedure-specific tool for objective evaluation of surgical performance during RARC. CASE may help differentiate novice from expert performances.

Keywords Robot-assisted · Radical cystectomy · Training · Skill acquisition · Quality · Assessment

Radical cystectomy (RC) with pelvic lymph node dissection (LND) represents the gold standard for management of non-metastatic muscle invasive bladder cancer and refractory non-muscle invasive disease. Recent interest has bolstered support for robot-assisted RC (RARC) aiming to improve perioperative outcomes, including blood loss, transfusion rates, hospital stay, and recovery without compromising oncological efficacy [1, 2]. Consequently, the past decade has witnessed a shift in the utilization of RARC (from $< 1\%$

Ahmed A. Hussein and Kevin J. Sexton had equal contribution.

✉ Khurshid A. Guru
Khurshid.Guru@roswellpark.org

1 Department of Urology, Roswell Park Cancer Institute, Elm and Carlton Streets, Buffalo, NY 14263, USA

2 Cairo University, Cairo, Egypt

3 University of California, San Francisco, CA, USA

4 Karolinska University Hospital, Stockholm, Sweden

5 Temple University Hospital, Philadelphia, PA, USA

6 University of Southern California, Los Angeles, CA, USA

7 Memorial Sloan Kettering Cancer Center, New York, NY, USA

8 Henry Ford Health Systems, Detroit, MI, USA

9 OhioHealth, Dublin, OH, USA

10 Stanford University, Palo Alto, CA, USA

11 University of Ulm, Ulm, Germany

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in 2004 to 13% in 2010) [2]. Nevertheless, much of the criticism to RARC has been attributed to the steep learning curve associated with this complex procedure. Moreover, there is no standardized way to what defines surgical proficiency for RARC, with some reports supporting at least 20–30 procedures to "flatten" the initial learning curve and then subsequently attempt more complex intracorporeal reconstructions [3].

With wide adoption of robot-assisted surgery in urology, the American Urologic Association highlighted the need for validated, procedure-specific tools to assess proficiency and assist in credentialing for robot-assisted procedures [4]. These tools should aim at objective quantification of surgical performance in a standardized manner using evidence-based quality indicators, and to provide structured feedback to trainees. In this context, we aimed to develop a structured scoring tool, the cystectomy assessment and surgical evaluation (CASE) that objectively measures and quantifies performance during RARC for men.

Methods

A multi-institutional study was conducted between April 2016 and May 2017 using de-identified videos of RARCs performed by expert surgeons, fellows, and chief residents. The study comprised three phases.

Phase 1: content development and validation

A panel of 10 experienced open and/or robotic surgeons developed the structure of CASE by deconstructing the critical steps of RARC into 9 key domains; each was assessed on a 1 to 5 Likert scale. Specific description for Anchors 1, 3, and 5 were provided, meanwhile each domain was assessed utilizing five anchors evaluating surgical principles, technical proficiency, and safety, where Anchor 1—represented worst, and Anchor 5—defined ideal performance.

Delphi methodology was utilized for validation of CASE structure and content. Anchor descriptions for each of the nine domains were assessed by the panel in terms of appropriateness of operative skill being assessed, concordance between the statement and the score assigned, and clarity and unambiguous of wording. Experts were contacted separately to provide their feedback on the content of CASE to minimize the "bandwagon" or "halo" effect.

Responses from the panel experts were then collected and analyzed by two independent coordinators (medical student and a Urology Fellow). The content validity index (CVI) was used to validate the scoring system [5]. CVI is the proportion of expert surgeons who rated each anchor description as 4 or 5 on the Likert scale. Consensus for an anchor description was considered when the CVI was ≥ 0.75. If for a given anchor the CVI was < 0.75, comments of the panel were incorporated by the coordinator and redistributed to the panel. The process was repeated until consensus was achieved (Fig. 1).

Phase 2: inter-rater reliability

Reliability is the ability of CASE to yield consistent results when utilized by different raters. Ten videos of different proficiency levels (for each domain) were assessed by the panel members. The videos were assigned randomly to reviewers so that each video was reviewed by at least four different raters. Raters were blinded to operator level of experience.

Phase 3: construct validation

Construct validation refers to the ability of CASE to differentiate between expert and novice performance. Scores given by the panel members for attendings and trainees (fellows and residents) were compared. All domains of the procedure were assessed except the "Control of Vascular Pedicle" domain, for which there were no available videos of trainees performing the step, and the LND domain, which has already been assessed using a previously validated tool dedicated for assessment of LND after RARC [6].

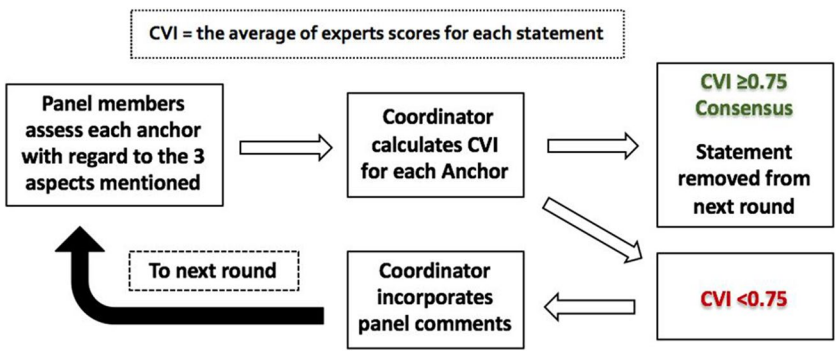

Fig. 1 Delphi methodology

Statistical analysis

Descriptive statistics were calculated for scores in each domain. A linearly weighted percent agreement was used to assess the inter-rater reliability. A logit model for odds ratio, which refers to the odds of an expert surgeon to score higher than 3 for a particular domain when compared to a trainee, was used to assess construct validation. Statistical significance was set at α level 0.05. All statistical analyses were performed using SAS 9.4 (SAS Institute, Cary, NC).

Results

Content development and validation

The expert surgeon panel included four open and six robotic surgeons (Table 1). All of the panel members perform LND routinely with RC, four of them perform it prior to bladder extirpation. Based on the panel consensus, domain 9 "Tissue Disposition and Specimen Removal" was removed from the scoring system. Consensus (CVI ≥ 0.75) was achieved for all statements after 4 rounds: 12 statements (11%) in the first round, 64 (61%) in the second, 25 (24%) in the third, and 4 (4%) after the fourth (Fig. 2). The final eight-domain CASE included: pelvic LND, development of the peri-ureteral space, lateral pelvic space, anterior rectal space, control of the vascular pedicle, anterior vesical space, control of the dorsal venous complex, and apical dissection (Fig. 3).

Table 1 Characteristics of the 10-surgeon panel which participated in development and validation of CASE

Panel characteristics	*n* (%)
Urology practice (years)	
5–10	2 (20)
10–20	6 (60)
> 20	2 (20)
Experience	
Formal RAS training	5 (50)
RAS performed > 500	4 (40)
Open RC performed > 500	5 (50)
RARC performed > 50	4 (40)
Procedural preferences	
Routinely performs LND with cystectomy	10 (100)
LND before cystectomy	4 (40)
LND after cystectomy	6 (60)
Standard LND template	1 (10)
Extended LND template	6 (60)
Super-extended LND template	3 (3)
Institutional characteristics	
Annual urologic procedure volume > 500	6 (60)
Annual RC volume > 50	6 (60)
Proportion of RC performed robot-assisted 25–50%	3 (30)
All RC performed robot-assisted	3 (60)

RAS robot-assisted surgery, *LND* lymph node dissection, *RC*, radical cystectomy

Reliability

Linearly weighted percent agreement was > 0.6 for all domains. The highest agreement was for "Anterior Vesical Space" (0.81), followed by "Apical Dissection" (0.76) and "Anterior Rectal Space" (0.75; Table 2).

Construct validation

The expert surgeon group outperformed the trainees in all domains assessed but did not reach statistical significance. The odds for experts to score higher than trainees were highest for "Apical dissection" [mean difference 0.6, OR 2.35, 95% confidence interval (CI) 0.52–10.74] and "Peri-ureteral Space" (mean difference 0.6, OR 2.16, 95% CI 0.63–7.47). It was least for "DVC Control" (mean difference 0.2, OR 1.09, 95% CI 0.27–4.47'; Table 3; Fig. 4).

Discussion

Continuous monitoring of surgical quality is a duty of modern day practice. Although outcomes are mainly driven by disease-related factors, the quality of operative management is mandatory for satisfactory outcomes [1, 7–9]. Variability between surgeons and institutions has been shown to significantly affect patient outcomes [10, 11]. It remains crucial to ensure adequate, comprehensive training of trainees to assure graduation of competent and safe surgeons. Although surgical simulators have been developed to allow surgical training without

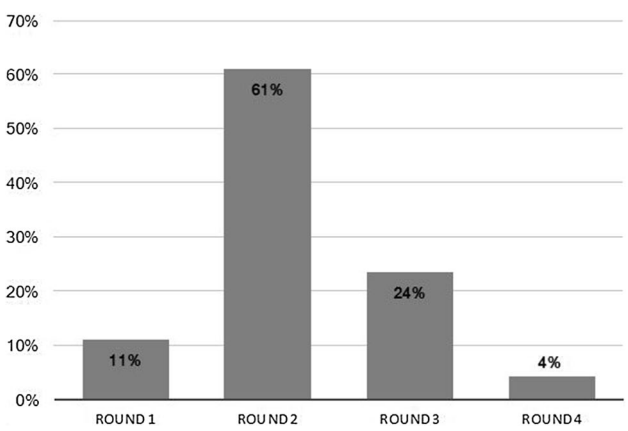

Fig. 2 Content development: consensus/round

Cystectomy Assessment and Surgical Evaluation (CASE)

DOMAINS*	1	2	3	4	5
Lymph Node Dissection [if LND Performed Before Radical Cystectomy]			Name:		
Lymph Node Dissection (LND)* ** [Not Intended for Detailed Assessment of LND, but only for Surgeons that Start Cystectomy with LND]	• No Lymphatic Tissue Removed: Non-visualization of Obturator Nerve or Iliac Vessels • Injury to Genitofemoral Nerve and/or Obturator Nerve and/or Iliac Vessels	2	• Inadequate Removal of Lymphatic Tissue: Partial Visualization of Obturator Nerve or Iliac Vessels • Triangle of Marcille* Not Defined	4	• Template-Appropriate Lymphatic Tissue Removed: Complete Visualization of the Obturator Nerve and Iliac Vessels • Triangle of Marcille* is Well-Defined
*defined Triangle of Marcille = mobilization of External Iliac Artery to retrieve lymphatic tissue at exit of Obturator Nerve from Psoas Muscle					
Peri-Ureteric Space			Name:		
Identify and Dissect Ureters Down to the Uretero-Vesical Junction (UVJ)	• Injury or Traumatic Handling of Ureter • Inadvertent Entry into Urinary Bladder • Injury to Iliac Vessels	2	• Difficulty Identifying Ureter • Excessive handling / De-Vascularization of Ureter • Inadequate Proximal Dissection of Ureter: Not Allowing a Tension -Free and Safe Anastamosis	4	• Atraumatic, Adequate Dissection to Allow Tension-Free and Safe Anastamosis • Adequate Peri-Ureteric Tissue
Lateral Pelvic Space			Name:		
Release of Urinary Bladder from the Lateral Pelvic Wall	• Incomplete Release of Urinary Bladder/Tumor from Lateral Pelvic Wall and Iliac Vessels • Entry into the Urinary Bladder/ Tumor • Injury to the Iliac Vessels/ Obturator Nerve • Non-visualization of EndoPelvic Fascia (EPF)	2	• Improper Surgical Plane +/- Entry into the Inguinal Space and/or Entry into Peri-Vesical Fat • Partial Visualization and Incomplete Opening of EPF	4	• Separation of the Bladder from the Lateral Pelvic Wall, Nerves, and Vessels: Properly Defining the Lateral Vascular Pedicle • Complete Visualization and Opening of the EPF
Anterior Rectal Space			Name:		
Release of Urinary Bladder from the Anterior Rectal Wall	• Incomplete Release of the Urinary Bladder and Prostate from the Anterior Rectal Wall • Wrong Plane with Entry into Urinary Bladder/Tumor, Prostate, Seminal Vesicles, or Rectum	2	• Wrong Plane, Too Close to Bladder or Rectum with Subsequent Correction	4	• Clean and Adequate Development of the Anterior Rectal Space down to the Prostatic Apex or Distal Urethra
Control of Vascular Pedicle			Name:		
Control of the Vascular Pedicle	• Injury to Vessels • Vascular Pedicle is Not Defined	2	• Vascular Pedicle is Incompletely Defined • Poor Control and bleeding from the Vessels	4	• Control of Vascular Pedicle with Insignificant Bleeding
Anterior Space of Retzius (Vesical)			Name:		
Release of Urinary Bladder from the Anterior Abdominal Wall/ Bladder Drop	• Inadvertent Entry into Urinary Bladder, Prostate or Anterior Abdominal Wall. • Injury to Inferior Epigastric Artery	2	• Wrong Plane with Tissue Left Anteriorly, Obscuring the Operative Field	4	• Clean Dissection from Abdominal Wall that Respects All Surgical Planes with Minimal Bleeding
Control of DVC			Name:		
Control of Dorsal Venous Complex (DVC)	• Inadvertent, Premature Entry into the DVC • Uncontrolled DVC Bleeding	2	• Incomplete Closure of DVC, Minor Bleeding • Need to Re-Suture	4	• Adequate Control of DVC with Minimal Bleeding
Apical Dissection			Name:		
Urethral Transection	• Spillage of Bladder or Urethral Contents • Inadequate Urethral Dissection (Non-Visualization of the Urethra) • Injury to Lateral Apical NVB (if Nerve-Sparing Performed)	2	• Partial Visualization of the Urethra with Inadvertent Entry into Prostate and Subsequent Correction • Excessive Shortening or Charring/ Cautery of Urethra (if Planned Orthotopic Diversion)	4	• Complete Visualization and Clean Division of the Urethra • No Spillage of Bladder or Urethral Contents • Preservation of the NVB (if Nerve-Sparing Performed)

* The presence of any single or multiple criteria within each anchor qualifies for that score.

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Fig. 3 CASE

Table 2 Inter-rater reliability for eight domains of CASE, using linearly weighted percent agreement

Domains	Agreement
Peri-ureteral space	0.68
Lateral pelvic space	0.73
Anterior rectal space	0.75
Vascular pedicle	0.72
Anterior vesical space	0.81
DVC control	0.71
Apical dissection	0.76

DVC dorsal venous complex

Table 3 Construct validation for eight domains of CASE: average scores for trainees and attending surgeons

Domains	Mean trainee score	Mean expert score	Odds ratio	95% Confidence interval
Peri-ureteral space	2.8	3.4	2.16	0.63–7.47
Lateral pelvic space	3.7	3.8	1.36	0.37–5.00
Anterior rectal space	3.5	3.7	1.70	0.28–10.51
Vascular pedicle	N/A*			
Anterior vesical space	4.0	4.6	N/A**	
DVC control	3.6	3.8	1.09	0.27–4.47
Apical dissection	3.8	4.4	2.35	0.52–10.74

N/A* no videos were available for trainees to assess this step, N/A** data were not enough for calculations

DVC dorsal venous complex

affecting patient outcomes, they have only shown limited predictive validity in transferring skills gained to the real operative environment [12]. Operating with robot assistance has become an integral aspect of modern urological practice; however, standards for competency are yet to be determined [13]. Overall number of procedures performed or console hours have been used suggested as a measure for technical proficiency. However, there is no sufficient evidence to support the use of either, with wide variation in the number of procedures required to achieve technical competency [12, 14]. This highlights the need for an objective and well-defined tool to assess surgical competency. The global evaluative assessment of robotic skills has been developed and validated to assess basic robot-assisted surgical skills (as depth perception, bimanual dexterity, etc.) but lacked procedure-specific goals [15]. Prostatectomy assessment and competency evaluation is a validated procedure-specific tool for radical prostatectomy that has been developed using a similar expert-based methodology by our group [16]. Prior studies have shown that what constitutes 'technical proficiency' varies widely among surgeons [14, 17]. To our knowledge, CASE is the first objective assessment tool for RARC developed using real surgical performances and with involvement of both open and robotic expert surgeons. Reliability of all steps has been demonstrated among the 10 experts. Utilizing the same principles, our group has developed and validated several objective, structured, and procedure-specific scoring tools for different robot-assisted procedures [6, 16, 18].

We utilized the Delphi methodology for development and content validation of CASE. This technique has been widely used across many disciplines as a method to seek expert opinion in a structured manner [19]. The key features of the method are anonymity between participants during building the consensus to prevent authority, reputation, or personality of some of the participants from dominating the process. Also, it allows provision of controlled feedback in a structured manner, where participants can adjust their initial ratings based on feedback from the group [19]. In the absence of a standardized definition of

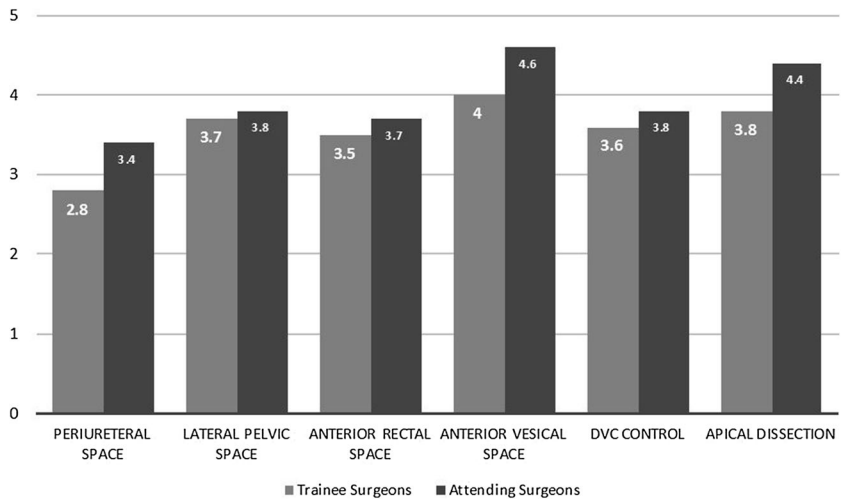

Fig. 4 Construct validation: mean scores (trainees vs. attendings) for each domain

what constitutes surgical proficiency for RARC, consensus of experts about surgical principles, oncological safety, and sound surgical technique can serve as evidence.

Video assessments may be subject to variation among different raters. However, assessments based on pre-defined criteria may decrease variation. Developing scoring tools to assess surgical performance, both in real-time and retrospective video recordings, can provide useful information and feedback for trainees. Birkmeyer et al. showed that assessment of surgical performance using video recordings can provide adequate and reliable measure for technical proficiency. The Michigan Bariatric Surgical Collaborative utilized a panel of 20 surgeons to review video performances of laparoscopic gastric bypass procedure and to rate them using validated scoring system including domains for tissue and instrument handling, exposure, time and motion, and surgical flow [20].

Deconstruction of a procedure into smaller modules (modular training) has been shown to be effective in transferring challenging surgical skills to trainees in a step-wise manner while simultaneously shorten the learning curve [21, 22]. The structure of CASE combines the principles of modular training with specific descriptions of the scores assigned to reduce any bias among raters. The scores can be further utilized to track the progress of trainees, and identify weaknesses and thereby guide and tailor training. Although skill-assessment tools have been developed to assess performance on simulators, the majority were not validated in a real operative setting [23]. CASE was able to distinguish between expert surgeons and trainees for all steps examined, although the results should be interpreted with caution due to the small number of video recordings, and the lack of wide variation among the videos, as most of the trainees were experienced (either chief residents or fellows) with significant console hours under their belt. RARC is a complex minimally invasive procedure. Therefore, higher trainee level with active participation during the procedures was included in this study. CASE has been developed and validated expert surgeons in the field and based on real operative performances to ensure skill acquisition based on procedure-specific goals.

The training of new surgeons in robotic surgery faces obstacles such as limited time for training (especially with the new duty-hour restrictions), high cost, and lack of well-defined standards and the need for ensuring oncologic safety [16, 24]. Ethical concerns in terms of disclosing the degree of trainees' participation and the potential higher risk of complications represent another key concern [25]. The high cost of the training equipment, such as simulators or setting up a fully equipped robot in an animal or dry lab is a big limitation [16]. In the OR, the isolation of the operating console surgeon away from the patient and any form of visual cueing or body language from the remotely placed mentor to the trainee adds an additional layer of complexity to the teaching process versus a hands-on approach (traditional open—or even laparoscopic environment), where the mentor remotely placed and cannot as readily redirect the trainee or intervene if needed [26].

CASE can serve as a standardized framework for the benchmarks for RARC. It can be used to evaluate trainee surgeons in the execution of the various steps of RARC and monitor their progress during their residency of fellowship training. The modular approach also ensures acquisition of the desired skills and the training program objectives. It can be used by institutions as a quality measure and for auditing performances, and credentialing and surgeon remediation. CASE has been shown to be highly reliable and yield similar results when applied by different raters, demonstrating its objectivity. The scoring system can be utilized consistently across various institutions, with various using a tool with consistent and standardized language. This is despite, and in contrast to, previously identified variation in what actually is meant by 'technical proficiency' among different surgeons [14, 17]. CASE, being very comprehensive in defining each proficiency level to minimize variation among raters, may be time consuming in the beginning. Using CASE can be a learning curve that once established, assessment can be easier and of shorter duration. We are currently creating an application that can be used on mobile phones. This application is also enhanced with illustrations describing each proficiency level. This may cut down the learning curve and simplify the process of using CASE.

Despite the uniqueness of this study, we encountered some significant limitations. First, there were no videos for trainees performing the "Control of Vascular Pedicle" step. A larger pool of videos with varying experience for the validation phase would have been more likely to achieve more statistical significance. Although the quality of surgical performance has been previously linked with outcomes, we did not correlate CASE scores with patient outcomes in the current study. Despite the importance of non-technical skills, such as communication, leadership, and decision making, CASE was specifically designed to only assess procedure-specific surgical skills.

Conclusion

We developed and validated a reliable structured, procedure-specific tool for objective evaluation of surgical performance during RARC. CASE may differentiate novice from expert performances. It can be used to provide structured feedback for surgical quality assessment and facilitate more effective training programs.

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Compliance with ethical standards

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