Safe introduction of laparoscopic and retroperitoneoscopic nephrectomy in clinical practice: impact of a modular training program.

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Abstract
Purpose To describe and validate a novel modular training scheme (MTS) for trans-peritoneal laparoscopic nephrectomy (LN) and retroperitoneoscopic nephrectomy (RN).
Methods Four consultant urologists attended a Masterclass in "Advanced Laparoscopic and Robotic Surgery," certified by the University of Turin (IT). The Masterclass was based on a supervised MTS, which involved progressive, proficiency-based training through nine and seven steps for LN and RN, respectively. After becoming proficient in all the steps, each trainee performed a minimum of five procedures as first operator under direct observation of the mentor in the training centre. Then, each trainee independently performed 10 LN and 10 RN at his home institution. The surgical outcomes were compared with those from a contemporary series of procedures performed by the mentor.
Results All trainees successfully completed the 12-week MTS program. Median number of training cases to become competent in trans-peritoneal LN and RN was 13.0 (IQR 11.5–20.5) and 23.5 (IQR 19.5–32.0), respectively. A significantly higher rate of conversion to open surgery was observed for RNs independently performed by the trainees in their hospital compared to the mentor ($p = 0.033$). Failure to progress due to difficult anatomical orientation and abdominal wall bleeding during dissection of retroperitoneal space were the most frequent reasons of conversion.
Conclusions A 12-week intensive modular program allows to achieve proficiency in performing independently LN and a RN after a median of 13 and 23.5 cases, respectively. Therefore, these procedures can be safely introduced and implemented in clinical practice within a relatively short time.
Keywords Modular training · Laparoscopic nephrectomy · Mentoring

Introduction

The proved clinical benefits of laparoscopic surgery have prompted its widespread diffusion over the past two decades. However, significant attention has been given on the specific challenges of this technique, and its steep learning curve, when compared to open surgery [1]. For this reason, laparoscopic training programs have been conceived and implemented in order to facilitate the dissemination of specific surgical skills related to laparoscopic surgery. The goal of laparoscopic training is to allow surgeons to become proficient in performing laparoscopic procedures, thus reducing the risk of complications, which are more

likely to be encountered at the beginning of the learning curve.

Available evidence suggests that laparoscopic hands-on training in a laboratory setting can be a good way to start [2, 3]. Its face, content, construct and concurrent validities have been largely reported, without significant differences between box training and virtual reality [2, 4–6]. Animal models have also been used to further improve laparoscopic skills, and the transition from dry laboratory to wet laboratory has been regarded by several authors as an essential part of the training process of a laparoscopic surgeon [7].

However, despite a myriad of reported training protocols, it is still a matter of debate how to adequately prepare trainees to “real life” scenarios in the operative room, and how to reach proficiency in the urologic laparoscopic procedures [1, 7]. For this reason, several fellowship and mentorship programs have been developed in order to allow a safe clinical implementation of urologic laparoscopy without increasing the risk of complications for the patients [8, 9].

A structured stepwise training scheme (modular training scheme, MTS) has been proposed and evaluated in the field of laparoscopic urologic surgery [3]. The MTS allows the mentor to determine whether the apprentice has acquired the required skills before embarking in the next (more challenging) step of a given procedure. On the other side, while the trainee performs each module till he has reached the level of proficiency, prompt intervention by the mentor is allowed whenever patient safety is in danger [1].

MTS has been largely popularized by Stolzenburg for laparoscopic radical prostatectomy [10, 11].

On the other hand, to the best of our knowledge, only one publication has described a modular approach for trans-peritoneal laparoscopic nephrectomy (LN) [12], whereas there is complete lack of studies regarding MTS for retroperitoneoscopic nephrectomy (RN).

Aim of this study was to test the effectiveness of a purpose-

built MTS in enabling practising urologists to safely introduce both laparoscopic and retroperitoneoscopic nephrectomy in their clinical practice.

Materials and methods

Study design and participants

Four consultant urologists with previous laparoscopic experience limited to laparoscopic assistant and laboratory training, completed a structured postgraduate training program (Masterclass in advanced laparoscopic and robotic surgery) offered by the University of Turin at San Luigi Gonzaga Hospital (Orbassano, Turin, Italy).

After completing the MTS program, each of them performed a minimum of five complete procedures (both LN and RN) under the guidance of a mentor at the teaching institution (F.P.). Then, each of the trainees performed their first “independent” (without the mentor in the room) trans-peritoneal LN (n = 10) and RN (n = 10) at their own centre. The surgical outcomes were compared with a contemporary series of similar procedures performed by the mentor surgeon.

The study was approved by the local hospital ethics committee and all patients signed written informed consent.

MTS program

The MTS consisted of a 12 non-consecutive weeks of “full immersion” in the operative room over a 1-year period. It was based on supervised modular training for both transperitoneal LN and RN, involving progressive, proficiencybased surgical steps with levels of increasing complexity.

Specifically, a nine-step program for the trans-peritoneal approach and a seven-step program for the retroperitoneal approach (Table 1) were developed by faculty members of Masterclass program.

The progressive steps were labeled as “modules,” and they were graded in accordance with the required skills from module 1 (the lowest level of difficulty) to module 5

(the highest level of difficulty) (Table 1).

The following selection criteria were adopted for cases of LN and RN: body mass index <30; no vascular abnormalities on preoperative contrast-enhanced CT-scan, in case of benign diseases, no suspected xanthogranulomatous pyelonephritis; no tumors over 10 cm in size.

The mentoring process was tailored to the individual trainee. The mentor decided in all cases whether the trainee could approach the following step of the procedure. When the trainee was considered ready (proficient) to carry out the full procedure, he was allowed to perform a minimum of five procedures as first operator under direct supervision of mentor [12, 13].

Data analysis

The impact of modular training on each participant was analyzed, evaluating the number of training cases needed to become proficient in each module, and to safely complete the full procedure as first surgeon.

Perioperative data (age, previous abdominal surgery, operative time, estimated blood losses, and rate of conversion to open surgery) and postoperative data (duration of hospitalization, complications, pathology analysis) of trans-peritoneal LN and RN independently carried out by trainees in their own centre, were prospectively collected in a dedicated database.

Descriptive analysis was performed for the collected variables. Categorical variables were reported as frequency and proportion and compared with the Pearson' Chi-square test. Continuous variables were reported as median and interquartile range (IQR) and compared with the analysis of variance, as appropriate. Statistical significance was set at $p < 0.05$. The statistical analysis was carried out by using SPSS v.18.0 (IBM Corp, Armonk, NY, USA).

Results

Demographics and previous surgical experience of the participants are reported in Table 2.

All trainees successfully completed the 12-week MTS

program. Median number of training cases during the duration of the program was 13.0 (IQR 11.5–20.5) and 23.5 (IQR 19.5–32.0) for trans-peritoneal LN and RN, respectively. The most difficult (module 5) among the surgical steps identified required the highest number of cases (both in trans- and retroperitoneal approach) to be managed by the trainees.

Surgical outcomes: trans-peritoneal laparoscopic nephrectomies performed without mentor

Median operative time ranged from 135.0 to 175.0 min, and median estimated blood loss (EBL) ranged from 135.0 to 250.0 ml with significant differences with respect to the mentor ($p < 0.001$). No transfusions were needed. Three intra-operative complications requiring conversion to open approach (two vascular injuries and a splenic injury managed with splenectomy) were recorded. No difference was recorded between the trainees and the mentor in the overall complication rate (Table 3).

Surgical outcomes: retroperitoneoscopic nephrectomies performed without mentor

Median operative time ranged from 130.0 to 165.0 min and median EBL from 120.0 to 250.0 ml, with significant differences compared with mentor ($p < 0.001$). A significantly higher rate of conversion to open surgery was observed among the trainees. Failure to progress due to difficult anatomical orientation and abdominal wall bleeding during dissection of retroperitoneal space were the most frequent reasons of conversion to open surgery. No significant differences were found in terms of postoperative complications and findings at histopathological analysis (Table 3).

Discussion

Laparoscopy has largely replaced open surgery in the management of kidney benign disease and localized kidney cancer not amenable to a nephron-sparing approach [14]. According to the European scoring system introduced by the European Section of Uro-Technology (ESUT-European Association of Urology) [15], LN may be considered as a moderately difficult procedure, which urologic surgeons have to face at early in their laparoscopic experience. Laparoscopic surgery is not easy to learn and bench training together with a MTS on real clinical cases can represent the best way to get adequate laparoscopic skills to safely carry out urological laparoscopic procedures [1, 3]. The concept of MTS was popularized by Stolzenburg et al. [10, 11] for laparoscopic radical prostatectomy, and it aimed to overcome the issues related to the teaching of a full complex procedure, while preserving patient safety and accelerating the learning curve of the trainee [16].

A recent systematic review stressed the importance of structured and modular mentorship programs, concluding that such programs are feasible and produce relevant results [17]. In the literature, we could find only one study focusing on MTS for trans-peritoneal LN [12]. In this study three trainees (two consultants and one resident), with variable laparoscopic background experience, were involved. Authors showed that their MTS could ease the learning curve during a period of 6 months, with the need of 17–32 cases during the training, followed by a short proctored

timeframe in the trainee's own centre.
In the present study, we evaluated a 12-week "mini- fellowship" program developed in a high volume laparoscopic hosting centre. In particular, the median number of training cases needed to get skills enough to complete trans-peritoneal LN without the help of the mentor was 13.0 (IQR 11.5–20.5) and 23.5 (IQR 19.5–32.0) for RN. These numbers are lower than those reported by Stewart et al. [12], probably because the trainees were all postgraduate physicians working already as consultants with some level of laparoscopic experience, and no residents were included. On the other side, the higher number of cases needed to be performed before embarking in RN without the mentor was probably related to the lower feeling with retroperitoneal access by the trainees.
In order to validate our MTS, we evaluated and compared the first 10 cases performed by the trainees in own hospitals to a contemporary series of 10 cases performed by the mentor: After comparison, an acceptable level of intra-operative and postoperative complications was found, but shorter operative time and lower estimated blood losses were recorded for the mentor in both trans- and retroperitoneal approach. Particularly, we observed, for the trainees, a higher number of intra-operative complications for RN if compared to trans-peritoneal LN. This finding can be explained by the more difficult recognition of main anatomical landmarks and dissection of surgical plan when working into retroperitoneal space.
Due to the low caseload analyzed in the present study, it was not possible to determine whether the trainees were able to manage major intra-operative complications, such as massive hemorrhage, without open conversion.
We are aware that an important problem is the access to modular training courses. A 2003 ESUT survey [18] showed that 44 % of the respondents had insufficient access to training programs. Unfortunately, there has not been any significant improvement during the last years. Recently, Brinkman et al. [19] investigated the level of laparoscopic skills of final-year residents in urology in Europe. The authors found that 61 % of the residents stated that they did not have the opportunity to receive structured training in laparoscopy during their residency. This unmet need for access to adequate training in laparoscopic techniques has been also showed by Furriell et al. [20]. The authors analyzed the results of a European survey among residents during the European Association Congress 2012, showing that 32 % of the residents did not attend any course or fellowship on laparoscopy and 42 % of the respondents did not have access to any type of laparoscopy laboratory in their institution.
In the literature, different models of courses and fellowship in departments with high laparoscopic volume (short courses, mini-apprenticeships and full time fellowships) have been explored as methods of training. We embrace the idea that a correct pathway toward appropriate training involves the experience with dedicated faculty members in residency or fellowships after residency, supplemented with a rich experience in surgical simulation and wet laboratory [1]. Institutions responsible for urological education should increase their efforts to extend training programs and to

facilitate their access on a national and international scale.

In addition, these programs should consider both technical and non-technical skills [3].
Last, but not least, another important issue is the obligation to certificate the training program and to ensure that certified training is appropriate and consistent with a standard. This issue is important, and its goal is to allow surgeons and their teams to be credentialed for each minimally invasive procedure, with the ultimate aim of optimizing patient's safety and surgical outcomes. Up to date, two basic curriculums for training and assessment of basic laparoscopic skills have been developed and reported in the literature: the European Basic Laparoscopic Urological Skills (E-BLUS) in Europe and the Fundamentals of Laparoscopic Surgery in USA (FLS) [20, 21]. It has been shown that they are valid in significantly improving basic laparoscopic skills. In addition, several international institutions developed and validated curricula for advanced laparoscopic training in the operative room [1]. However, these curricula do not always include modular training and they have been validated in relation to specific procedures only, i.e., laparoscopic radical prostatectomy. To the best of our knowledge, our modular training program represents the first modular training scheme for both trans-peritoneal LN and RN certified by a public institution (University of Turin) as part of its postgraduate programs.
Our study is not devoid of limitations. First, the number of trainees included in the study was limited. Second, the trainees had previous non-homogeneous experience with laparoscopic surgery, and this could affect the outcomes recorded in the study. Third, the number of training cases needed to became competent in LN and RN was determined in a subjective fashion by the mentor and there was no objective or qualitative measurements supporting the achievement of proficiency in different steps. For this reason, these study findings would still require external validation in other hospital setting and with involvement of different mentors. Fourth, there was no specific training of "non-technical" skills.

Conclusion

A 12-week intensive modular program allows to achieve proficiency in performing independently trans-peritoneal LN and a RN after a median of 13 and 23.5 cases, respectively. Therefore, these procedures can be safely introduced and implemented in clinical practice within a relatively short time. Further studies are needed to externally validate these findings and to better define the ideal modular training program for these urological laparoscopic procedures.

Author's contribution Protocol/project development were done by Cantiello F, Porpiglia F. Data collection or management were performed by Cantiello F, Bertolo R, Fiori C and Cicione A. Data analysis were done by Cantiello F, Veneziano D and Cicione A. Manuscript writing/editing were done by Cantiello F, Porpiglia F. Supervision was done by Autorino R, Damiano R, Porpiglia F.

Compliance with ethical standards

Ethical standard The ethics committee of University of Turin approved this study. All patients were given their informed consent prior to their inclusion in the study. This article contains no personal information of any patients enrolled.

Conflict of interest Each author declares no conflict of interest.

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