Quality Assessment of Partial Nephrectomy Complications Reporting Using EAU Standardised Quality Criteria

Dionysios Mitropoulos a,*, Walter Artibani b, Chandra Shekhar Biyani c, Jørgen Bjerggaard Jensen d, Mesut Remzi e, Morgan Roupré f, Michael Truss g

a 1st Department of Urology, University of Athens Medical School, Athens, Greece; b Department of Surgery, Urology Clinic, University of Verona, Verona, Italy; c Department of Urology, Pinderfields General Hospital, Wakefield, United Kingdom; d Department of Urology, Aarhus University Hospital, Skejby, Denmark; e Department of Urology, Landesklinikum Korneuburg, Korneuburg, Austria; f Academic Department of Urology, Hospital Pitie-Salpétrière, Assistance Publique Hopitaux de Paris, Faculté de Médecine Pierre et Marie Curie, University Paris 6, Paris, France; g Department of Urology, Klinikum Dortmund GmbH, Dortmund, Germany

Abstract

Context: A standardised system to report outcomes and complications of urologic procedures has recently been proposed by an ad hoc European Association of Urology (EAU) Guidelines panel. To date, no studies have used these criteria to evaluate the quality of reports of outcomes and complications after partial nephrectomy (PN).

Objective: To address the quality of reporting of PN complications.

Design, setting, and participants: A systematic review of papers reporting outcomes of PN was conducted through the electronic search of databases, including Medline, PubMed, Embase, Scopus, and the Cochrane Database of Systematic Reviews.

Outcome measurements and statistical analysis: Analysis was carried out on structured forms. The quality criteria that the EAU Working Group proposed for reporting complications were recorded for each paper, and adherence to the Martin criteria was assessed.

Results and limitations: Standardised criteria to report and grade complications were used in 71 out of 204 evaluable studies (34.8%). Only six studies (2.9%) fulfilled all criteria that the EAU Guidelines Office ad hoc panel proposed. The mean number did not change significantly by time or by surgical approach used. The most underreported criteria (in <50% of the studies) were who collected the data (18.6%), whether he or she was involved in the treatment (13.7%), duration of follow-up (47.1%), mortality data and causes of death (33.8%), definition of procedure-specific complications (39.2), separate reporting of intra- and postoperative complications (45.1%), complication severity or grade (32.4%), risk factors analysis (44.1%), readmission rates (12.7%), and percentage of patients lost to follow-up (6.9%). The mean number fulfilled was 6.5 ± 2.9 (mean plus or minus standard deviation) and did not change significantly by time or by surgical approach used.

Conclusions: The only way to improve the quality of the surgical scientific literature and to allow sound comparisons among different approaches, especially with the lack of randomised trials, is the use of more rigorous methodology than the one recently proposed to report outcomes and complications.

Patient summary: A rigorous methodology is mandatory when surgeons report about complications after surgery. Otherwise, the rate of adverse events is underestimated.

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1. Introduction

Safety and quality have become prominent criteria by which surgical care is evaluated. The need for hospitals and surgeons to present the quality of care that they provide is now stronger than ever, because it is requested by patients as well as by health care providers and payers in the public and private sector. The measurement and reporting of outcomes and complications following surgery are a fundamental process to improving the quality and safety of care that a health system provides, both in terms of the health framework and delivery of care by institutions and the individual clinicians themselves [1,2]. It is theoretically desirable to have a minimum set of outcomes measured and reported in clinical research, allowing differing interventions to be compared and contrasted with greater ease and reducing the risk of outcome reporting bias. Evidence exists that contemporary reporting of outcomes and complications data are based on flawed methodologies that potentially mislead and deceive. Such deceptions may harm patients, surgeons, and hospitals in various ways and could undermine quality of surgical care and patients’ access to it [3–5]. Currently, there is no agreed-upon standard about what and how information is recorded and reported; hence, there is no consistency in the data available for extraction.

In response to these concerns about the quality of reporting of complications, in 2002 Martin et al. developed 10 criteria by which to judge the quality of complication reporting. They observed a largely inconsistent approach to the definition, measurement, and reporting of all types of complications in the literature [6]. Recently, the ad hoc European Association of Urology (EAU) ad hoc panel on complication reporting proposed concrete guidelines for “the development and implementation of a standardised reporting system that focuses on patient-centred outcomes” [7].

Surgery is the only curative therapeutic approach for the treatment of renal cell carcinoma (RCC), while partial nephrectomy (PN) is now widely accepted as the standard treatment for small renal masses, yielding virtually identical oncologic outcomes as radical nephrectomy in appropriately selected patients [8–10]. However, there is a lack of uniform reporting of outcomes and complications, especially with the evolution of novel surgical approaches.

Our purpose was to ascertain whether it was feasible to use the quality criteria proposed by the EAU Working Group [7] as a standardised outcome measure for reporting complications after PN and to assess to which degree these criteria were met in the current literature.

2. Materials and methods

A systematic review was conducted based on a literature search through the electronic search of databases, including Medline and PubMed, Embase, Scopus, and the Cochrane Database of Systematic Reviews. Medical Subject Headings terms and keywords included were partial nephrectomy, nephron-sparing surgery, complications, grading, and classification. Search was limited to literature in the English language.

After exclusion of abstract only, duplicates, articles with <20 cases, paediatric series, review articles, expert comments, PN for trauma, angiomyolipoma, stones, and tuberculosis, we identified 204 articles published in 29 journals from 1996 to 2012. The full text of these articles was reviewed. All the data retrieved from the selected studies were recorded in an electronic database. The quality criteria that the EAU Working Group proposed for reporting complications [7] were recorded for each paper. In addition, we assessed adherence to the Martin criteria [6]. Disagreement among reviewers was resolved by consensus by all authors.

3. Results

The vast majority of papers (97%) were published after 2000. Most studies were case series (n = 184; 90.2%), while the rest of them were controlled studies without randomisation (n = 20; 9.8%). The surgical approach used was open (43 studies), laparoscopic (87 studies), hand-assisted laparoscopic (5 studies), robot-assisted laparoscopic (27 studies), and several in 42 studies.

The level of evidence (LoE) according to the taxonomy used in the EAU guidelines was 2a (well-designed, controlled studies without randomisation) in 16 studies (7.8%), 2b (well-designed quasi-experimental study) in 1 study (0.5%), and 3 (well-designed nonexperimental studies such as comparative studies, correlation studies, and case reports) in 187 studies (91.7%). Standardised criteria by which to report and grade complications were used in 71 studies (34.8%). These criteria were predefined by the authors in 7 studies (9.9%), proposed by Clavien-Dindo [11] in 48 (67.6%), and offered by several others in 16 (22.5%). The proportion of studies using standardised criteria to report and grade complications increased significantly by time (χ², p < 0.001).

Fulfilment of the Martin criteria is shown in Table 1. All 10 criteria were fulfilled in only 8 studies (3.9%); 9, 8, 7, 6, and 5 criteria were fulfilled in 15 (7.4%), 18 (8.8%), 19 (9.3%), 53 (26%), and 40 (19.6%) studies, accordingly. The mean number was 5.6 ± 2.19 (mean plus minus standard deviation [SD]; range: 0–10) and did not change significantly by time or by the surgical approach used (analysis of variance [ANOVA], p > 0.05).

Fulfilment of the criteria proposed by the EAU Guidelines Office ad hoc panel is shown in Table 2. Only six studies (2.9%) fulfilled all criteria. The most underreported criteria (in <50% of the studies) were who collected the data.

Table 1 – Fulfilment of the Martin criteria

<table>
<thead>
<tr>
<th>Criteria</th>
<th>No.</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method of accruing data defined</td>
<td>181</td>
<td>88.7</td>
</tr>
<tr>
<td>Duration of follow-up indicated</td>
<td>124</td>
<td>60.8</td>
</tr>
<tr>
<td>Outpatient information included</td>
<td>101</td>
<td>49.5</td>
</tr>
<tr>
<td>Definitions of complications provided</td>
<td>74</td>
<td>36.3</td>
</tr>
<tr>
<td>Mortality rate and causes of death listed</td>
<td>66</td>
<td>32.4</td>
</tr>
<tr>
<td>Morbidity rate and total complications indicated</td>
<td>175</td>
<td>85.8</td>
</tr>
<tr>
<td>Procedure-specific complications included</td>
<td>162</td>
<td>79.4</td>
</tr>
<tr>
<td>Severity grade used</td>
<td>69</td>
<td>33.8</td>
</tr>
<tr>
<td>Length-of-stay data</td>
<td>140</td>
<td>68.6</td>
</tr>
<tr>
<td>Risk factors included in the analysis</td>
<td>67</td>
<td>32.8</td>
</tr>
</tbody>
</table>
was skill-demanding, discouraging for surgeons [13,14]. Developed, but the learning curve of pure laparoscopic NSS minimally invasive laparoscopic approaches have been tumour, leaving a kidney remnant [9]. In recent years, excellent oncologic results comparable to radical nephrectomy (ie, solitary kidney, bilateral or hereditary tumours, or moderate to severe renal insufficiency). According to the current guidelines, however, NSS is now recommended for all cases of RCCs (>90%) on NSS been included, but the learning curve of pure laparoscopic NSS was skill-demanding, discouraging for surgeons [13,14]. Thus, the introduction of pure laparoscopic renal surgery has paradoxically led to a decrease in the use of PN in the United States [15]. Despite its cost, robot-assisted laparoscopic PN has emerged progressively as the natural evolution of pure laparoscopic NSS [16], which has in turn led to an increase in the threshold of complexity of renal masses that surgeons are willing to attempt to excise robotically [17–19]. Interestingly, even NSS gained interest at the end of the last century: We found that only four studies (<50%) in our series of NSS reports: definition of complications reporting using EAU standardised quality criteria.

Overall, 161 series (79%) were reported within the past 5 yr. The vast majority of these reports did not investigate the complication rates of NSS in relation to the surgical approach used, and there was a lack of a standardised reporting system (ie, <32% of cases). However, the proportion of studies using standardised criteria to report complications increased significantly over the period of the time studied. This is in accordance with our previous report on the change of urologists’ attitude towards using standardised systems to report complications [7].

Nine or 10 Martin criteria were fulfilled in only 23 studies (11.3%). When Donat studied the general urologic oncology literature in 2007, she found a corresponding percentage of 2% [20]. The most commonly underreported (<50%) Martin criteria in our study were outpatient information (49.5%), definitions of complications (36.3%), inclusion of risk factors in the analysis (32.8%), mortality rates and causes of death (32.4%), and complication severity or grade (33.8%; Table 1). In Donat’s report, the corresponding entities were duration of follow-up, outpatient information, definition of complications, inclusion of procedure-specific complications, complication severity or grade, and inclusion of risk factors [20].

The criteria we recently proposed are more explicit than the Martin criteria; only a few of them were included accurately in >50% in our series of NSS reports: definition of recommendation within the context of current and reliable guidelines. This is indeed a fact for NSS, because the vast majority (>90%) of the studies on the matter were well-designed nonexperimental studies, such as comparative studies or case series, and were assigned an LoE of 3.

In 2002, Martin proposed 10 criteria that should be considered when reporting complications following surgery [6]. In 2012, an ad hoc panel of the EAU Guidelines Office stated that a uniformed reporting of complications after urologic procedures was mandatory. Accordingly, a list of quality criteria was proposed [7]. Certain criteria were similar between the lists. In the current study, our purpose was to explore the quality assessment of NSS complications reporting using EAU standardised quality criteria.

### Discussion

Nephron-sparing surgery (NSS) for localised RCC has four goals: oncologic control, maintenance of renal function, low morbidity, and surgical reproducibility [12]. Historically, it was proposed only in imperative cases in patients who would have otherwise been on dialysis after radical nephrectomy (ie, solitary kidney, bilateral or hereditary tumours, or moderate to severe renal insufficiency). According to the current guidelines, however, NSS is now recommended for all cases of RCCs (<7 cm (T1) because of excellent oncologic results comparable to radical nephrectomy, leaving a kidney remnant [9]. In recent years, minimally invasive laparoscopic approaches have been developed, but the learning curve of pure laparoscopic NSS

<table>
<thead>
<tr>
<th>Method of accruing data (retrospective or prospective)</th>
<th>187</th>
<th>91.6</th>
</tr>
</thead>
<tbody>
<tr>
<td>How data were accrued (chart review, telephone interview, face-to-face interview, other)</td>
<td>174</td>
<td>85.3</td>
</tr>
<tr>
<td>Who collected the data (medical doctor, nurse, data manager, other)</td>
<td>38</td>
<td>18.6</td>
</tr>
<tr>
<td>Was he or she involved in the treatment? (yes or no)</td>
<td>28</td>
<td>13.7</td>
</tr>
<tr>
<td>Duration of follow-up (30, 60, 90, &gt;90 d)</td>
<td>96</td>
<td>47.1</td>
</tr>
<tr>
<td>Outpatient information included</td>
<td>102</td>
<td>50.0</td>
</tr>
<tr>
<td>Mortality data and causes of death included</td>
<td>69</td>
<td>33.8</td>
</tr>
<tr>
<td>Definitions of complications included</td>
<td>80</td>
<td>39.2</td>
</tr>
<tr>
<td>Procedure-specific complications defined</td>
<td>80</td>
<td>39.2</td>
</tr>
<tr>
<td>Separate reporting of intra- and postoperative complications</td>
<td>92</td>
<td>45.1</td>
</tr>
<tr>
<td>Severity grading system for postoperative complications used</td>
<td>66</td>
<td>32.4</td>
</tr>
<tr>
<td>Postoperative complications were presented in a table either by grade or by complication type</td>
<td>104</td>
<td>51.0</td>
</tr>
<tr>
<td>Risk factors were included (ASA score, CCI, ECOG, other)</td>
<td>90</td>
<td>44.1</td>
</tr>
<tr>
<td>Readmissions and causes were included</td>
<td>26</td>
<td>12.7</td>
</tr>
<tr>
<td>Reoperations, types, and causes were included</td>
<td>106</td>
<td>52.0</td>
</tr>
<tr>
<td>Percentage of patients lost to follow-up was included</td>
<td>14</td>
<td>6.9</td>
</tr>
</tbody>
</table>

ASA = American Society of Anesthesiologists; CCI = Charlson Comorbidity Index; ECOG = Eastern Cooperative Oncology Group.
the method of accruing data, morbidity rate/total complications, and length-of-stay data. Surprisingly, at the bottom of the list, we found that the following criteria were missing in the vast majority of published series: who collected the data and whether he or she were involved in the treatment, duration of follow-up, mortality data and causes of death, definition of procedure-specific complications, separate reporting of intra- and postoperative complications, complication severity or grade, risk factors analysis, readmission rates, and percentage of patients lost to follow-up (Table 2). One possible explanation is that the mortality rate and thus the causes of death listed are in fact zero in the vast majority of cases. However, for quality reasons, it has to be mentioned adequately. The percentage of patients lost to follow-up was only mentioned in 14 studies (6.9%). Ou and Zimmern recently showed that even in randomised clinical trials for surgical treatment of benign prostatic hyperplasia, only 15% reached the Consolidated Standards of Reporting Trials statement for patients lost to follow-up. Even more, the increase in patients lost to follow-up over time compromised the strength of the conclusion from the leftover patient population [21].

Surprisingly, we found that the mean number of the EAU and/or Martin criteria fulfilled changed significantly neither by time nor by surgical approach used. The Clavien-Dindo classification and grading of complications [11] is well known in the urologic community, as 67.6% of studies used it [7], but many of the recent studies used a scoring system to describe the complexity of the procedure but not another structured system to report complications. This underlines that urologists are probably trying to be honest while aiming to report their series by spontaneously using certain criteria that belong to clinicians’ common sense. In other words, surgery evolves, but the surgeons continue with bad habits in scientific writing over time.

It was also surprising that only 32.8% of the studies included risk factors for complication analyses. One possible explanation is that the majority (90.2%) were case series analyses in a retrospective manner, and thus known risk factors like comorbidities, complexity of the tumour, and preoperative kidney function were not reported.

5. Conclusions

The basic purpose of the EAU as a scientific association is to achieve the highest level of urologic care within Europe and beyond. In the absence of randomised trials, the only way to improve the quality of care would be to improve the quality of the surgical scientific literature by means of a more rigorous methodology for reporting outcomes and complications with sound comparison.

One might ask whether the proposed EAU criteria are redundant, need revision, or even miss important parameters. This is why we decided to assess our EAU criteria in a focused area of oncourology (ie, conservative surgery in RCC), as we thought it would be an efficient way to achieve a “validation” of our list. In addition, we strongly believe that this improvement would likely revive a renewed interest in daily clinical practice in the minds of surgeons. Moreover, it would allow recommendations for the use of procedures that would result in fewer complications, clearly the most relevant issue in improving patient care.

Author contributions: Dionyios Mitropoulos had 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: Mitropoulos, Artibani, Bjerggaard Jensen, Remzi, Rouprêt, Truss.

Acquisition of data: Biyani, Bjerggaard Jensen, Remzi, Rouprêt.

Analysis and interpretation of data: Mitropoulos, Artibani, Biyani, Bjerggaard Jensen, Remzi, Rouprêt, Truss.

Drafting of the manuscript: Mitropoulos, Artibani, Biyani, Bjerggaard Jensen, Remzi, Rouprêt, Truss.

Critical revision of the manuscript for important intellectual content: Mitropoulos, Artibani, Biyani, Bjerggaard Jensen, Remzi, Rouprêt, Truss.

Statistical analysis: Mitropoulos.

Obtaining funding: None.

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Supervision: Mitropoulos.

Other (specify): None.

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