Guidelines on Reporting and Grading of Complications after Urologic Surgical Procedures

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1. INTRODUCTION

Evidence of variations in clinical practice, together with rising costs associated with constrained resources in most health care systems over the past decade, has triggered growing interest in evaluating the quality of our surgical work (1-3). At present, the main methods of assessing surgical results for audit and quality assurance remain mortality and morbidity (4-6). Thus measurement of morbidity requires an accurate definition of a surgical complication. Although the incidence of postoperative complications is still the most frequently used surrogate marker of quality in surgery (1,3,7), the direct cause-and-effect relationship between surgery and complications is often difficult to assess. This uncertainty carries a risk of underreporting surgical complications, with substantial consequences.

Most published articles focus only on positive outcomes (e.g. trifecta in prostate cancer after radical prostatectomy) (8). There is a need to compare complications for each specific approach in a systematic, objective, and reproducible way. As yet, no definitions for complications or guidelines for reporting surgical outcomes have been universally accepted. Reporting and grading of complications in a structured fashion is only one aspect of the quality of outcome reporting. In 2002, Martin et al. proposed 10 criteria that should be met when reporting complications following surgery (9) (Table 1). Clavien and Dindo proposed a system for grading the severity of postoperative complications (10) that was subsequently revised and validated (11) (Table 2).

Table 1: Martin et al. criteria of accurate and comprehensive reporting of surgical complications (9)

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method of accruing data defined</td>
<td>Prospective or retrospective accrual of data are indicated</td>
</tr>
<tr>
<td>Duration of follow-up indicated</td>
<td>Report clarifies the time period of postoperative accrual of complications such as 30 days or same hospitalisation</td>
</tr>
<tr>
<td>Outpatient information included</td>
<td>Study indicates that complications first identified following discharge are included in the analysis</td>
</tr>
<tr>
<td>Definition of complications provided</td>
<td>Article defines at least one complication with specific inclusion criteria</td>
</tr>
<tr>
<td>Mortality rate and causes of death listed</td>
<td>The number of patients who died in the postoperative period of study are recorded together with cause of death</td>
</tr>
<tr>
<td>Morbidity rate and total complications indicated</td>
<td>The number of patients with any complication and the total number of complications are recorded</td>
</tr>
<tr>
<td>Procedure-specific complications included</td>
<td>Any grading system designed to clarify severity of complications including major and minor is reported</td>
</tr>
<tr>
<td>Severity grade utilised</td>
<td>Length-of-stay data Median or mean length of stay indicated in the study</td>
</tr>
<tr>
<td>Risk factors included in the analysis</td>
<td>Evidence of risk stratification and method used indicated by study</td>
</tr>
</tbody>
</table>

Table 2: Clavien-Dindo grading system for the classification of surgical complications (11)

<table>
<thead>
<tr>
<th>Grades</th>
<th>Definitions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade I</td>
<td>Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic and radiological interventions. Acceptable therapeutic regimens are: drugs such as antiemetics, antipyretics, analgesics, diuretics and electrolytes, and physiotherapy. This grade also includes wound infections opened at the bedside.</td>
</tr>
<tr>
<td>Grade II</td>
<td>Requiring pharmacological treatment with drugs other than those allowed for grade I complications. Blood transfusions and total parenteral nutrition are also included.</td>
</tr>
<tr>
<td>Grade III</td>
<td>Requiring surgical, endoscopic or radiological intervention</td>
</tr>
<tr>
<td>Grade III-a</td>
<td>Intervention not under general anaesthesia</td>
</tr>
<tr>
<td>Grade III-b</td>
<td>Intervention under general anaesthesia</td>
</tr>
<tr>
<td>Grade IV</td>
<td>Life-threatening complication (including CNS complications: brain haemorrhage, ischaemic stroke, subarachnoid bleeding, but excluding transient ischaemic attacks) requiring IC/ICU management</td>
</tr>
<tr>
<td>Grade IV-a</td>
<td>Single organ dysfunction (including dialysis)</td>
</tr>
<tr>
<td>Grade IV-b</td>
<td>Multi-organ dysfunction</td>
</tr>
<tr>
<td>Grade V</td>
<td>Death of a patient</td>
</tr>
<tr>
<td>--------</td>
<td>-------------------</td>
</tr>
<tr>
<td>Suffix “d”</td>
<td>If the patient suffers from a complication at the time of discharge the suffix “d” (for disability) is added to the respective grade of complication. This label indicates the need for a follow-up to evaluate the complication fully.</td>
</tr>
</tbody>
</table>

Despite these proposals, no current standard guidelines or criteria exist for reporting surgical complications in the area of urology. It appears important that the urologic community create universally accepted criteria for reporting surgical morbidity and outcomes to establish the efficacy of surgical techniques and improve the quality of patient care (12). Adopting an integrated method of characterising and reporting surgical morbidity has the potential to improve patient care on many levels:

- It enables better characterisation of surgical morbidity associated with various surgical techniques.
- It allows comparison of different surgical techniques, which is important due to the relative lack (< 1%) of randomised trials in the urologic literature.
- It allows the physician to portray more accurately to patients the risks of a procedure versus other surgical or medical options.
- It allows better sequencing of multimodality approaches.
- It allows earlier recognition of the pattern of complications, thereby allowing for pre-emptive changes in care in an effort to decline the incidence.
- It allows better comparisons between individual surgeons or between institutional experiences.
- It allows identification of quality-of-care measures for benchmarking.

The aim of our work was to review the available reporting systems used for urologic surgical complications, to establish a possible change in attitude towards reporting of complications using standardised systems, to assess systematically the Clavien-Dindo system (currently widely used for the reporting of complications related to urologic surgical interventions), to identify shortcomings in reporting complications, and to present recommendations for the development and implementation of future reporting systems that focus on patient-centred outcomes. The panel did not take intraoperative complications into consideration, which may be addressed in a follow-up project.

1.1 Publication history
This article presents a republication of a scientific paper published in European Urology, the EAU scientific journal (13). Prior to publication, the paper has been subjected to double blind peer review.

In the course of 2012 the authors aim to assess the usage and reproducibility of the proposed model for reporting of complications. These findings will be published upon completion of the assessment.

2. EVIDENCE ACQUISITION

Standardised systems for reporting and classification of surgical complications were identified through a systematic review of the literature. To establish a possible change in attitude towards reporting of complications related to urologic procedures and assessment of the Clavien-Dindo system in urology, two different strategies were used. For the first objective (reporting trends), papers reporting complications after urologic surgery published in European Urology, Journal of Urology, Urology, BJU International, and World Journal of Urology in 1999-2000 and 2009-2010 were reviewed. Selection criteria were the top five general urology journals (from major urologic societies) based on impact factor (IF) and English-language publications. The panel recognised that IF as a quality indicator was debatable but considered that it would have had no impact on the validity of the outcome of this review. Promising articles were identified initially through the tables of contents of the respective journals. All selected papers were full-text retrieved and assessed; papers not reporting complications and reviews were excluded from the analysis. Analysis was done based on a structured form, which was similar for each article and for each journal (Form 1).

Data identification for the second objective (systematic assessment of the Clavien-Dindo system currently used for reporting of complications related to urologic surgical interventions) involved a Medline/Embase search using Clavien, urology, and complications as keywords. This search produced 63 eligible papers reporting complications using the Clavien-Dindo system. A second search using the search engines of individual urologic journals and publishers that may identify Clavien or Dindo and urology within the full text of a paper produced
141 more papers. Thus the total number of eligible papers was 204. All selected papers were full-text retrieved for analysis, which was done based on a structured form (Form 2). All papers were evaluated by two authors independently, and in case of disagreement, the paper was presented to all members to reach consensus.

Form 1: Data extraction form to assess reporting of complications after urological procedures using the Clavien-Dindo system

<table>
<thead>
<tr>
<th>Study title:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Published in:</td>
<td></td>
</tr>
</tbody>
</table>
- European Urology  
- Journal of Urology  
- BJU International  
- Urology  
- World Journal of Urology |
| Year of publication: |  
- 1999/2000  
- 2009/2010 |
| The study is a: |  
- Case series  
- Controlled study without randomisation  
- Prospective, randomised trial  
- Meta-analysis |
| Level of evidence (Oxford criteria, EAU modification): |  
- 1a  
- 1b  
- 2a  
- 2b  
- 3 |
| The study reports complications after (define the procedure): |  |
| Did the authors use standardised criteria? |  
- Yes  
- No |
| In case standardised criteria were used, they were: |  
- Predefined by authors  
- Clavien-Dindo system |
| No of Martin criteria met: |  
- 0-2  
- 3/4  
- 5/6  
- 7/8  
- 9/10 |

Form 2: Data extraction form to assess reporting of complications after urological procedures using the Clavien-Dindo system

<table>
<thead>
<tr>
<th>Study title:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Published in:</td>
<td></td>
</tr>
<tr>
<td>Year of publication:</td>
<td></td>
</tr>
</tbody>
</table>
- Volume: page to |
| The study is a: |  
- Case series  
- Controlled study without randomisation  
- Prospective, randomised trial  
- Meta-analysis |
| Level of evidence (Oxford criteria, EAU modification): |  
- 1a  
- 1b  
- 2a  
- 2b  
- 3 |
| No of Martin criteria met (0-10): |  |
| The study reports complications after (define): |  |
| In your opinion, was the Clavien-Dindo system used correctly? |  
- Yes  
- No |
| If NO, why not: |  |
3. EVIDENCE SYNTHESIS

3.1 Systems used to report surgical complications
The systematic review of the literature for standardised systems used for reporting and classification of surgical complications revealed five standardised systems (Table 3).

Table 3: Available classification systems for reporting of complications

<table>
<thead>
<tr>
<th>Classification</th>
<th>Clinical validation</th>
<th>Simplicity</th>
<th>Severity grading</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clavien-Dindo</td>
<td>Yes</td>
<td>Easy</td>
<td>I-V</td>
</tr>
<tr>
<td>MSKCC</td>
<td>Yes</td>
<td>Easy</td>
<td>5</td>
</tr>
<tr>
<td>Accordion</td>
<td>No</td>
<td>Easy</td>
<td>4, 6</td>
</tr>
<tr>
<td></td>
<td>contracted extended</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NSQIP</td>
<td>Yes</td>
<td>Complex</td>
<td>Major/minor</td>
</tr>
<tr>
<td>NCT-CTC</td>
<td>Yes</td>
<td>Complex</td>
<td>5</td>
</tr>
</tbody>
</table>

MSKCC = Memorial Sloan-Kettering Cancer Centre classification - modification of the original T92 Clavien classification (9,14); NSQIP = National Surgical Quality Improvement Programme (3); NCT-CTC = National Cancer Institute Common Toxicity Criteria (17).

In 1992, Clavien et al. proposed a classification for complications of surgery and introduced a severity grading system called T92 (10), which was based on the main criterion of the intervention needed to resolve the complication. Four grades containing five levels of complications were described. In 2004, Dindo et al. introduced a modification of the T92 classification using five grades containing seven levels (Table 2) (11). This modification was performed to add further precision and to characterise whether an intervention due to the complication led to general anaesthesia, intensive care unit admission, or organ failure, and again, it was based on the type of therapy required to treat the complication. This modified classification, which is known as the Clavien-Dindo system, was validated and tested for interobserver variation in 10 centres around the world (14). The Clavien-Dindo system is widely used, with an exponential increase in recent years, especially in general surgery but also in urology (see Fig. 3 and 4). A few authors have adapted both systems to analyse specific procedures such as liver donor liver and kidney transplantation, which has led to confusion (14).

A less extensive modification of the T92 system was made by Martin et al. (9), and (15) and is referred to as the Memorial Sloan-Kettering Cancer Centre (MSKCC) severity grading system; conceptually, it is very similar to T92 but differs in numbering (for details see Table 1 in Strasberg et al. [16]).

The Accordion classification was introduced in 2009 and represents a flexible system that can be used in studies of different size and complexity (17) (Table 4). It is available on an open Web site (http://www accordionclassification.wustl.edu).
Table 4: Accordion severity classification of postoperative complications: contracted and expanded classification (17)

<table>
<thead>
<tr>
<th>Contracted classification</th>
<th>Expanded classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Mild complication</td>
<td>1. Mild complication</td>
</tr>
<tr>
<td>Requires only minor invasive procedures that can be done at the bedside, such as insertion of intravenous lines, urinary catheters and nasogastric tubes, and drainage of wound infections. Physiotherapy and the following drugs are allowed: antiemetics, antipyretics, analgesics, diuretics and electrolytes.</td>
<td>Requires only minor invasive procedures that can be done at the bedside, such as insertion of intravenous lines, urinary catheters and nasogastric tubes, and drainage of wound infections. Physiotherapy and the following drugs are allowed: antiemetics, antipyretics, analgesics, diuretics and electrolytes.</td>
</tr>
<tr>
<td>2. Moderate complication</td>
<td>2. Moderate complication</td>
</tr>
<tr>
<td>Requires pharmacological treatment with drugs other than those allowed for minor complications, for example, antibiotics. Blood transfusions and total parenteral nutrition are also included.</td>
<td>Requires pharmacological treatment with drugs other than those allowed for minor complications, for example, antibiotics. Blood transfusions and total parenteral nutrition are also included.</td>
</tr>
<tr>
<td>All complications requiring endoscopic or interventional radiology or re-operation, as well as complications resulting in failure of one or more organ systems.</td>
<td>Requires management by an endoscopic, interventional procedure or re-operation without general anaesthesia</td>
</tr>
<tr>
<td>4. Death</td>
<td>4. Severe: operation under general anaesthesia</td>
</tr>
<tr>
<td>Postoperative death</td>
<td>Requires management by an operation under general anaesthesia</td>
</tr>
<tr>
<td></td>
<td>5. Severe: organ system failure†</td>
</tr>
<tr>
<td></td>
<td>6. Death Postoperative death</td>
</tr>
</tbody>
</table>

*An example would be wound re-exploration under conscious sedation and/or local anaesthetic.
†Such complications would normally be managed in an increased acuity setting but in some cases patients with complications of lower severity might also be admitted to an ICU.

The National Surgical Quality Improvement Program was established in 1994 within the US Veterans Administration (VA) health care system, with the aim of identifying and reporting adverse events as one prerequisite for process improvement in health care (3). The system is validated, outcome based, and uses data adjusted for patient preoperative risk. It allows comparison of the performance of different hospitals performing major surgery by the ratio of observed to expected (O/E) adverse events. Statistically low (O/E < 1) or high (O/E > 1) outliers are then identified to support continuous quality improvement activities. The annual use of this system has contributed to the improvement of the standard of surgical care and to lower 30-d mortality and morbidity rates for major noncardiac surgery within the VA.

The National Cancer Institute Common Toxicity Criteria (NCI-CTC) system (17) was first created in 1983, aimed at the recognition and grading of adverse effects of chemotherapy in cancer patients. The system was updated and expanded in 1998 (CTC v2.0), including acute effects of radiotherapy and limited criteria applicable to surgery. In 2003, Common Terminology Criteria for Adverse Events (CTCAE v3.0) was introduced for application to all possible modalities and is organised by organ system categories (all organs are included), with 370 different criteria. An adverse event is defined as any new finding or undesirable event that may not be attributed to treatment. Grading criteria are shown in Table 5. Late and acute effects criteria are merged into a single uniform system and applied without a predetermined time-based designation. The previously used “90-day rule” is not advised currently because each study is unique. The new CTC system was designed to be applied to all possible modalities, and it is organised by organ system categories (all organs are included) with 370 different criteria. The unexpected serious and life-threatening (grades 3 and 4) consequences of surgery are the focus of immediate surgical reporting. CTCAE v3.0 is available on the Cancer Therapy Evaluation Program Web site (www.ctep.info.nih.gov).
Table 5: National Cancer Institute Common Toxicity Criteria grading system for the adverse effects of
cancer treatment (17)

<table>
<thead>
<tr>
<th>Grade</th>
<th>Definition of effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade 1</td>
<td>Minimal and usually asymptomatic that do not interfere with functional endpoints (interventions or medications are generally not indicated for these minor effects).</td>
</tr>
<tr>
<td>Grade 2</td>
<td>Moderate, are usually symptomatic. Interventions such as local treatment or medications may be indicated (they may interfere with specific functions but not enough to impair activities of daily living).</td>
</tr>
<tr>
<td>Grade 3</td>
<td>Severe and very undesirable. There are usually multiple, disruptive symptoms (more serious interventions, including surgery or hospitalisation, may be indicated).</td>
</tr>
<tr>
<td>Grade 4</td>
<td>Potentially life threatening, catastrophic, disabling, or result in loss of organ, organ function, or limb.</td>
</tr>
</tbody>
</table>

Most recently, the International Urogynecological Association (IUGA) and the International Continence Society (ICS) have established a joint working group on terminology for complications related to the insertion of prostheses and grafts in female pelvic floor surgery (18). The document proposes definitions of specific complications, distinguishing local complications, complications to surrounding organs, and systemic complications. New terms have been proposed and defined in detail such as contraction, prominence, separation, exposure, extrusion, perforation, dehiscence, and sinus tract formation. The classification is based on category, time, and site of complications, with the aim of summarising any of a large range of possible clinical scenarios into a code using as few as three numerals and three (or four) letters. Lowercase letters can be added, describing the presence and the type of pain. The ICS-IUGA classification appears at first sight to be complex and not immediately mastered, as outlined by the proponents. The main goal is to establish common language and to promote a homogeneous registry to improve the quality of pelvic floor surgical procedures using prostheses and grafts.

3.2 Attitude of urologists towards reporting complications

A total of 874 eligible papers of 1261 retrieved publications were included in the final analysis. The type of studies reporting complications did not vary between the two time frames selected (1999-2000 vs 2009-2010) (p > 0.1). Most of the papers identified were case studies (Fig. 1). However, a shift could be seen in the number of studies using most of the Martin criteria (Fig. 2), as well as in the number of studies using either standardised criteria or the Clavien-Dindo system to report complications (Fig. 3).

Fig. 1: Comparative distribution of papers reporting complications after urologic procedures by study type and time frame
3.3 Assessment of the Clavien-Dindo system for reporting complications after urologic procedures

The literature search identified 204 papers published in:

- Urology 38
- Journal of Urology 37
- Journal of Endourology 35
- European Urology 34
- BJU International 19
- World Journal of Urology 15
- and several others 26

The number of papers using the Clavien-Dindo system to report complications after urologic surgical interventions showed an exponential increase (Fig. 4). Most of the studies identified were, again, case series, and 77.9% of the studies fulfilled ≥ 7 of the Martin criteria (range: 3-10; mean: 7.5; standard deviation: 1.5). The
vast majority of papers referred to novel technologies (laparoscopy/robot-assisted procedures), whereas only 13.2% of papers discussed open procedures. The Clavien-Dindo system was not properly used in 72 papers (35.3%): Eight times it was also used to report/grade intraoperative complications; six times the authors used their own modification of the Clavien-Dindo system; in 27 studies, the authors grouped complications into major (Clavien-Dindo ≥ 3) and minor without mentioning specific complications; and in 31 papers, the authors did not assign a grade to the complications reported.

Fig. 4: Distribution of studies using the Clavien-Dindo system to report complications after urologic procedures

3.4 Discussion
The definition of surgical complications still lacks standardisation, which hampers the interpretation of surgical performance and quality assessment (5,7,19). Although many surgeons would argue that their subjective intuition is an appropriate guide to defining what a complication might be, the value of the surgeon’s intuition is unreliable in many situations because it lacks objective criteria and depends heavily on the experience of the individual clinician (4,7,20). Second, a surgical complication is not a fixed reality. Instead, it depends on the surgeon’s level of skill, the surgeon’s learning curve for the procedure, the patient’s comorbidity and risk factors, and the facilities available. A surgical complication in a Western country may not be perceived or subjectively weighted as a surgical complication in rural or less developed countries. Similarly, a complication in 2011 may be seen as obsolete within a few years’ time, with a better understanding of the pathophysiology of the underlying malady. As surgical techniques and equipment improve, what were once inevitable negative outcomes may acquire the status of mere surgical complications (2,5,7). Finally, and paradoxically, the higher the expectation of the surgeon and patient, the more potential surgical complications occur (21,22). The clinical relevance of reporting surgical complications is primarily related to the fact that the dissemination of technology is very rapid, with current grades of recommendations based on the level of evidence in their corresponding studies. However, in the surgical field, randomised controlled trials with high levels of evidence are uncommon, and this limitation naturally leads to a low number of recommendations. We have to keep in mind that the guidelines can only rely on the surgical evidence. Thus there is a real discrepancy between the reality of daily surgical practice and the relevance of the low-grade recommendations produced in this area. However, the scientific quality of an article is not only related to its level of evidence. The use of more rigorous methodology and the consensus-related complications of surgical techniques will probably improve the quality of the surgical scientific literature. It is likely that this improvement will renew interest in daily clinical practice in the minds of surgeons. In addition, it will allow recommendations that avoid complications, clearly the most relevant issue in improving patient care.

In defining surgical complications, subjectivity cannot always be avoided, but it should be reduced as much as possible (4). Additionally, different audiences (e.g. patients, nurses, health care providers, and third-party payers) and different surgical communities (e.g. urologists, orthopaedists, and vascular surgeons) view, define,
and perceive complications differently. Currently, no generally accepted standards or definitions exist with regard to the severity of surgical complications. Clavien-Dindo recommended the following definitions of surgical outcomes:

1. Surgical complication: Any deviation from the ideal postoperative course that is not inherent in the procedure and does not comprise a failure to cure;
2. Failure to cure: Diseases or conditions that remained unchanged after surgery;
3. Sequelae: Conditions that are inherent in a procedure and thus would inevitably occur such as scar formation or the inability to walk after an amputation.

Based on the review of the current literature, and with reference to the Accordion Severity Grading System (16), an appropriate definition of a complication is a combination of the following items: an event unrelated to the purposes of the procedure, an unintended result of the procedure, an event occurring in temporal proximity to the procedure, something causing a deviation from the ideal postoperative course, an event that induces a change in management, or something that is morbid (i.e. causes suffering directly by causing pain or indirectly by subjecting the patient to additional interventions).

In contrast to a complication, the sequelae of a procedure should be defined as an after-effect of that procedure. The risk of sequelae is inherent in the procedure (e.g. diabetes after pancreatic resection, rejection after transplantation, limp after amputation, dyspnoea after pneumonectomy, or impairment of renal function after tumour nephrectomy). Failure to cure should be defined as failure to attain or maintain the purpose of the procedure (e.g. failure to remove all stones during ureteroscopy or percutaneous stone surgery, tumour recurrence, stricture recurrence, or recurrence of patency when the purpose of the procedure is to occlude). Sequelae of procedures and failures to cure should be reported but presented separately from complications (14).

However, a complication that results in lasting disability is considered a sequela of a complication. Stroke or acute renal failure (ARF) occurring after a procedure is considered a complication and should be reported as such. However, long-term aphasia resulting from stroke or chronic renal failure after ARF is considered a sequela of that complication. Therefore, it should be reported in a special section devoted specifically to long-term disability.

Patients and their treating physicians do not necessarily mean the same thing when they use the term complication. Several studies have shown substantial discrepancies in the reporting of adverse events and sequelae of a treatment when the estimations of patients and physicians are compared (22). The usual information on potential complications that patients can obtain before a surgical procedure can be taken from the available literature, the specific information given by the treating centre (i.e. home page or patient information brochures), or from direct discussion with the treating surgeon. This information has the potential to be biased from the definition of what is considered a complication, and a standardised system that is not only used for complication reports in the literature but also for patient counselling is important for a realistic estimation of outcomes. In the present literature, patients often report a higher frequency and severity of adverse events compared with that reported by their physicians (23). However, in a recent randomised study, Steinsvik et al. showed that several adverse events, such as bowel problems, were overrated by the physician (24). Overrating and especially underrating of complications by the treating physician leads to confusion and a discrepancy between patient expectation and reality.

Schroeck et al. evaluated variables associated with satisfaction and regret after open and robotic radical prostatectomy (21). Patients who underwent robotic-assisted laparoscopic prostatectomy were more likely to be regretful and dissatisfied, which was not necessarily interpreted as caused by a worse outcome but potentially caused by the higher expectation associated with an innovative procedure. The authors therefore suggested that urologists should carefully portray the risks and benefits of new technologies during preoperative counselling to minimise regret and maximise satisfaction.

Theses examples support the notion that realistic counselling is crucial for the patient’s decision-making process and for satisfaction with the achieved result. However, a standardised reporting system for surgical complications can only try to standardise the reporting of the intraoperative and perioperative morbidity of the procedure itself. Short-, mid- or long-term sequelae of a surgical procedure, such as erectile dysfunction or urinary incontinence following radical prostatectomy, are not covered by this classification and need to be reported with other validated tools.

Standardised classification and severity grading of surgical complications is essential for proper interpretation
of surgical outcome data, for comparing the surgical outcomes between institutions or individual surgeons, and for comparing techniques in case randomised trials are either lacking or difficult to perform (i.e. comparison of minimally invasive techniques with open surgery). The urologic community seems to conform to the current demands because recent studies have more often used standardised criteria to report complications (48.3% vs. 35.3%) (Fig. 3). In urologic oncology reports published from January 1995 to December 2005, the corresponding percentage was 33%, with only 19% (6% of the total) using a numerical complication severity grading system (12). The Clavien-Dindo system has gained wide acceptance both in general surgery (14) and the urologic community (Fig. 3, and Fig. 4). Clinical databases designed and controlled by physicians may underreport complications (25). Similarly, a disadvantage of the Clavien-Dindo system is its unreliability when recording is performed by residents, although, when captured, grading of complications was correct in 97% of the cases. Consequently, the authors have proposed that dedicated personnel should evaluate surgical outcomes (2). Special attention should also be paid to proper use of the Clavien-Dindo system because it has not been designed/validated to grade intraoperative complications, and any modifications and revisions can be confusing (14).

Classification and severity grading of surgical complications is an important, albeit not the only criterion of quality when reporting surgical outcome. Approximately 40% of general surgery series and trials and 23% of studies reporting surgical complications in urologic oncology (2) fulfil seven or more Martin criteria. Interestingly, 77.9% of the papers that used the Clavien-Dindo system to report complications after urologic procedures fulfilled seven or more criteria, a fact implying that its use contributes to higher quality reports.

Besides the efficiency of an individual surgeon and the function of an institution, surgical care outcomes also depend on the patient’s preoperative risk factors (26). Thus they should always be defined and used in the analysis and report. A substantial proportion of postoperative complications occur after hospital discharge (27); extension of the length of postoperative observation may therefore be necessary. Other quality-of-care indicators are readmissions and reoperations (28) and should be included in both preliminary and final reports.

4. CONCLUSIONS

There is an urgent need for uniform reporting of complications after urologic procedures, which will aid all those involved in patient care and scientific publishing (authors, reviewers, and editors). Urologists have considerably changed their attitude towards using standardised criteria when reporting complications, and there has been an exponential increase of the number of papers using the Clavien-Dindo system. However, a certain number of papers (35.3%) did not use it properly. When reporting the outcomes of urologic procedures, the committee proposes the following:

• Define your complications.
• Preferentially use a standardised system; the Clavien-Dindo grading system is highly recommended.
• When using the Clavien-Dindo system, provide a table of all complications and corresponding grades or list the complications by grade.
• Use the NCI-CTC system in multimodality treatment.
• Improve reporting of complications by following the revised quality criteria (Table 6).
• Define the method of accruing data: retrospective/prospective; through chart review/telephone interview/face-to-face interview/other.
• Define who collected the data: medical doctor/nurse/data manager/other, and whether he or she was involved in the treatment.
• Indicate the duration of follow-up: 30, 60, 90, or >90 d.
• Include outpatient information.
• Include mortality data and causes of death.
• Include definitions of complications.
• Define procedure-specific complications.
• Use a severity grading system (avoiding the distinction minor/major); the Clavien-Dindo system is recommended.
• Include risk factors: American Society of Anaesthesiologists score, Charlson score, Eastern Cooperative Oncology Group, other.
• Include readmissions and causes.
• Include reoperations, types and causes
• Include the percentage of patients lost to follow-up.
Finally, editors of urologic journals should demand the use of a standardised system to report complications after urologic surgery.

Table 6: Quality criteria for accurate and comprehensive reporting of surgical outcome

1. Define the method of accruing data:
   - retrospective _ prospective _ , through:
     - chart review _ telephone interview _ face to face interview _ other _

2. Define who collected the data:
   - medical doctor _ nurse _ data manager _ other _
   - and whether he/she was involved in the treatment: yes _ no _

3. Indicate the duration of follow-up:
   - 30 days _ 60 days _ 90 days _ > 90 days _

4. Include outpatient information

5. Include mortality data and causes of death

6. Include definitions of complications

7. Define procedure-specific complications

8. Report intraoperative and postoperative complications separately

9. Use a severity grading system for postoperative complications (avoiding the distinction minor/major) - Clavien-Dindo system is recommended

10. Postoperative complications should be presented in a table either by grade or by complication type (specific grades should always be provided; grouping is not accepted)

11. Include risk factors
   - ASA score _ Charlson score _ ECOG _ other _

12. Include readmissions and causes

13. Include re-operations, types and causes

14. Include the percentage of patients lost to follow-up

5. REFERENCES


6. ABBREVIATIONS USED IN THE TEXT

This list is not comprehensive for the most common abbreviations

ARF    acute renal failure
ASA    American Society of Anesthesiologists
CNS    central nervous system
CTC AE  Common Terminology criteria for Adverse Events
EAU    European Association of Urology
ECOG   Eastern Cooperative Oncology Group
IC(U)  intensive care (unit)
ICS    International Continence Society
IF     impact factor
IUGA   International Urogynecological Association
MSKCC  Memorial Sloan-Kettering Cancer Centre classification
NSQIP  National Surgical Quality Improvement Programme
NCT-CTC National Cancer Institute Common Toxicity Criteria
O/E    ratio of observed versus expected
VA     US Veterans Administration

Conflict of interest

All members of the ad hoc EAU Guidelines working group on Reporting and Grading Complications after Urologic Surgical Procedures have provided disclosure statements of all relationships which they have and which may be perceived as a potential source of conflict of interest. This information is kept on file in the European Association of Urology Central Office database. This guidelines document was developed with the financial support of the European Association of Urology. No external sources of funding and support have been involved. The EAU is a non-profit organisation and funding is limited to administrative assistance and travel and meeting expenses. No honoraria or other reimbursements have been provided.