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ARTICLE

Does every Clavien-Dindo complication matter? A national multi-center study in kidney cancer surgery

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ABSTRACT

Background: There is huge variation in Clavien-Dindo (CD) complication rates in urology. We sought to optimize the use of the CD system in kidney tumor surgery.

Methods: We retrospectively analyzed 1,286 patients undergoing kidney tumor operations in 12 Finnish hospitals during 2016–2017. Primary CD assignments were made by site urologists. Data were centrally reviewed by two authors in consensus meetings. Consistency of the primary assignments was assessed by the number of cases requiring correction. Complication load was compared as different outcome rates between five university hospital regions.

Results: The overall complication rate in primary data was 40% (517/1286) and varied significantly from 32 to 62% ($p < 0.001$) between the regions. The need for corrections in central review was significantly greater for CD1 (54%) compared to CD2 (16%, $p < 0.001$) and CD3-5 (11%, $p < 0.001$) categories. The final data comprised 500 CD complications after 390 surgeries. The most frequent pathologies were bleeding (8.4%), urological complications (5.9%) and postoperative fever (4.7%). The overall CD2 complications rate was statistically ($p < 0.001$) higher in region D and that of CD3-5 was higher ($p = 0.007$) in region B. In multivariable analysis, university hospital region, male sex, BMI $\geq$ 27, ECOG $\geq$ 1, partial nephrectomy type and open surgery significantly increased the risk of complications.

Conclusions: Comparative use of CD1 complications may be too inconsistent and only CD2-5 complications should be reported. Central review of the primary data and detailed guidelines are necessary.

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Introduction

Quality is a modern megatrend in healthcare [1]. A widely recognized criterion of surgical procedures is the presence or absence of postoperative complications. It is very important to compare different surgical procedures, their results or surgical quality regarding a specific procedure between institutions or surgeons. Consistency and reliability of recording and analysis of complications are of primary importance.

In 1992, Clavien et al. [2] introduced a systematic classification method to assess the severity of postoperative complications. The original classification consisted of four grades and was modified in 2004 to include seven grades [3]. The new Clavien-Dindo (CD) classification system was found to be simple and reproducible with minimal inter-observer variability [4]. In 2012, the European Association of Urology (EAU) guideline panel released ad hoc recommendations with 14 criteria on recording, grading and reporting on complications after urological surgery [5].

Despite both the CD system and the EAU recommendations along with the increasing adherence to these guidelines, huge variations still exist in reported complication rates in urology. The rate of postoperative complications ranged from 9–40% after radical prostatectomy [6,7] and from 12–38% after partial nephrectomy [8,9]. The variation of outcome may indicate differences in surgical quality or, most probably, inconsistency in the way complications are recorded.

Specific challenges and shortcomings are confronted when the CD system is implemented in surgical subspecialties. Recently, a survey of 174 EAU committee members was conducted in order to validate CD performance in a urology setting [10]. A total of 35 clinical scenarios were rated for CD by 81 members, most of whom had academic affiliations and

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familiarity with the CD system. However, the inter-rater agreement on all cases using Fleiss' kappa was only moderate ($k = 0.4$).

de la Rosette et al. [11] released a standardized list of 70 typical complication management scenarios with recommended CD assignments to facilitate the use of CD in urology. The lists compiled by Dindo et al. [3] and by de la Rosette et al. [11] are still the most important guidelines for the implementation of the CD system in urology.

In this study, we aimed to optimize the use of the CD system by central reviewing in order to get a better tool for registration of postoperative complication load.

Materials and methods

Study cohort

The study was approved by the ethics committee of the Hospital District of Helsinki and Uusimaa (HUS/3571/2017) and by the corresponding institutional boards of all the other hospitals that participated in this study.

All 17 hospitals in five university hospital regions (A, B, C, D, E) performing kidney tumor surgery in Finland were contacted and 12 hospitals (3/5 for A, 3/3 for B, 2/2 for C, 2/3 for D and 2/4 for E) including all the university hospitals participated in the study. The number of operations in the five hospitals that did not participate in the study was estimated to be 180, based on a recent Nordic surgical quality survey [12]. All consecutive kidney tumor operations with curative or cytoreductive indications, performed between 1 January 2016 and 31 December 2017, were included. Eleven patients with multiple tumors operated on at different times were handled as separate patients.

Data collection

The principal investigators for each site (sPIs) reviewed digitalized patient charts and collected the following data: age, sex, physical performance as defined by the Eastern Cooperative Oncology Group performance status (ECOG) [13], the Charlson Comorbidity Index CCI 2011 [14], body mass index (BMI), the American Society of Anesthesiologists (ASA) score [15], type of nephrectomy (partial/radical), modality of surgery (open/laparoscopy/robot-assisted), size of the tumor (cm) and preoperative s-creatinine (μmol/l). The three most important postoperative complications within 90 days after the operation were recorded with structured choices of diagnosis and treatment. Urological complications included perirenal urine collection, urinary infection, perirenal abscess, ischemic injuries, ureteral injury, urinary retention and acute kidney injury. Perirenal hematoma, bleeding from the renal parenchyma, hematuria and pseudoaneurysm were classified under the category of bleeding. The severity of the complications was assigned a CD score by the sPIs (primary data). CD subcategories a and b were combined in the analyses. The sPIs were asked to describe the complications and treatments in a written record, if they were uncertain about the classifications.

Review of the primary data

The primary CD assignments were centrally reviewed and, when required, corrected to deliver the final data by two authors (K.E., H.N.), according to the available guidelines, literature and opinions presented at the consensus meetings of the study members. Twenty-two selected clinical scenarios were discussed at the consensus meetings and are presented in Supplementary Table S1.

Statistical analyses

Continuous variables were described as median (quartiles) and were statistically compared by using the Kruskall-Wallis test. Categorized variables were compared by the Chi-squared test. Consistency of the primary CD assignments was evaluated using the number of corrections needed in the review process. Complication load was analyzed according to the overall rate (all complications divided by the number of patients) and morbidity (the number of patients with any complications and grading of the most severe complication). The variables that were significantly ($p < 0.05$) associated with morbidity of CD2-5 complications in univariable Chi-squared tests were included in the multivariable logistic regression analysis with a stepwise backward selection. p-values <0.05 were considered as statistically significant. SPSS Statistic software (version 29, IBM, Chicago, IL) was used for the calculations.

Results

Patient characteristics

The study cohort comprised 1,286 kidney tumor operations and made up 88% (1,286/1,469 nationwide) of the operations performed during the study period. The flowchart of patients is shown in Supplementary Figure S1. Demographic and clinical characteristics are shown in Table 1. There were minor differences in patient age, comorbidities, type of surgery and surgical approach between the university hospital regions.

Primary data and the central review

A total of 517 CD1–5 complications were primarily recorded after 408 kidney tumor operations. Thus, the overall complication rate was 40% (517/1286) but varied significantly ($p < 0.001$) from 32–62% between the five university regions. In the central review, 125 (24%) of 517 primary CD1–5 and additionally 22 CD0 complications were corrected to create the final data. The need for corrections was significantly greater for CD1 (71/131, 54%) compared to CD2 (41/263, 16%, $p < 0.001$) and CD3–5 (13/123, 11%, $p < 0.001$). The overall complication rates in the primary data were compared against the final data by using CD categories over the five university regions (shown in Figure 1).

Table 1. Demographic and clinical characteristics by university hospital regions.

Characteristics	University hospital region					*p*-value
	A	B	C	D	E	
Number of operations	585	213	208	141	139	
Male, *n* (%)	350 (60)	129 (61)	132 (63)	82 (58)	75 (54)	0.503
Age, median (IQR)	67 (58–73)	70 (60–76)	68 (59–73)	67 (59–74)	66 (59–73)	0.049
BMI, median (IQR)	27 (24–31)	27 (24–30)	27 (24–31)	27 (24–31)	28 (25–32)	0.745
CCI, *n* (%)						
0–1	452 (77)	150 (70)	132 (63)	110 (78)	115 (83)	<0.001
≥ 2	133 (33)	63 (30)	76 (37)	31 (22)	24 (17)	
ECOG, *n* (%)						
0–1	447 (84)	180 (85)	188 (90)	116 (82)	125 (90)	0.096
≥ 2	82 (16)	32 (15)	20 (10)	25 (18)	14 (10)	
Missing data, *n*	56	1				
ASA, *n* (%)						
1–2	274 (47)	100 (47)	86 (41)	73 (52)	58 (42)	0.3
3–4	311(53)	113 (53)	122 (59)	68 (48)	81(58)	
Type of nephrectomy, *n* (%)						
Radical nephrectomy	305 (52)	137 (64)	135 (65)	94 (67)	96 (69)	<0.001
Partial nephrectomy	280 (48)	76 (36)	73 (35)	47 (33)	43 (31)	
Surgical approach, *n* (%)						
Open	313 (53)	113 (53)	69 (33)	71 (50)	53 (38)	<0.001
Laparoscopy[a]	191(33)	100 (47)	139 (67)	42 (30)	71 (51)	
Robot-assisted	81 (14)	0	0	28 (20)	15 (11)	

[a] traditional and hand-assisted.
ECOG, Eastern Co-operative Oncology Group; CCI, Charlson comorbidity index (2011); IQR inter-quartile range.

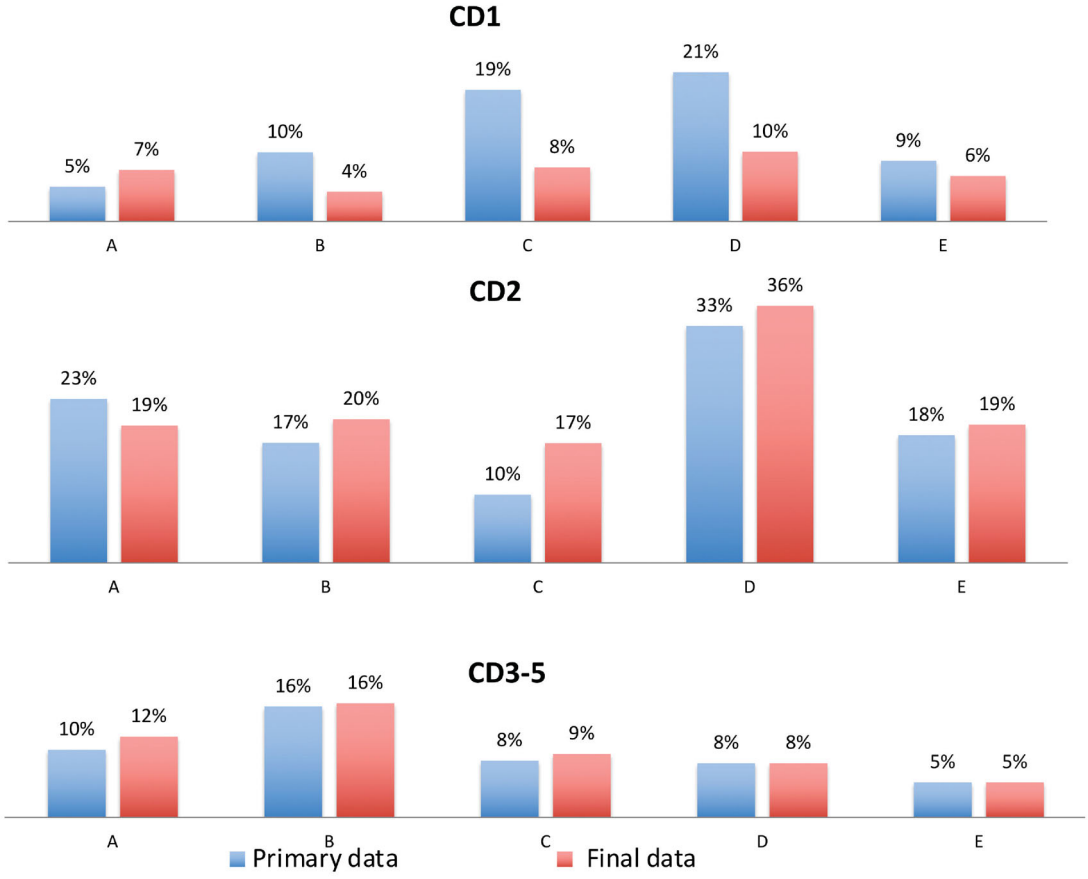

Figure 1. Postoperative overall complication rates after renal tumor surgeries performed in five university hospital regions (A, B, C, D and E) in Finland are stratified by Clavien-Dindo (CD) grade 1, 2 and 3–5 and presented as the primary data (blue) and the final data (red) after the central review.

The final data

The final data after the review comprised 500 CD1–5 complications after 390 operations and the overall complication rate was 39% (500/1,286), but this varied significantly ($p < 0.001$) from 30–54% between the university regions (Figure 1). The organ systems and pathologies associated with the complications and CD grades are presented in Table 2. The most frequent complications were bleeding (8.4%), urological complications (5.9%) and postoperative fever (4.7%). Nine

Table 2. Overall rates of Clavien-Dindo complications by associated organ systems and pathologies among 1,286 kidney tumor operations.

	Clavien-Dindo grade, *n* (%)					
Organ system/pathology	1	2	3	4	5	1–5
Bleeding	4 (0.3)	58 (4.5)	41 (3.2)	5 (0.4)	0	108 (8.4)
Urological	33 (2.6)	23 (1.8)	13 (1.0)	7 (0.5)	0	76 (5.9)
Abdominal wall	13 (1.0)	11 (0.9)	19 (1.5)	0	0	43 (3.3)
Gastrointestinal	15 (1.2)	31 (2.4)	15 (1.2)	1 (0.1)	1 (0.1)	63 (4.9)
Cardiovascular	2 (0.2)	43 (3.3)	4 (0.3)	10 (0.8)	1 (0.1)	60 (4.7)
Pulmonary	7 (0.5)	30 (2.3)	7 (0.5)	4 (0.3)	1 (0.1)	49 (3.8)
Neurological	10 (0.8)	3 (0.2)	0	4 (0.3)	1 (0.1)	18 (1.4)
Other	7 (0.5)	70 (5.4)	0	1 (0.1)	5 (0.4)	85 (6.6)
All	91 (7.1)	269 (21)	99 (7.7)	32 (2.5)	9 (0.7)	500 (39)

Overall rate is defined as the number of all complications based on the final data for 1,286 kidney tumor operations.

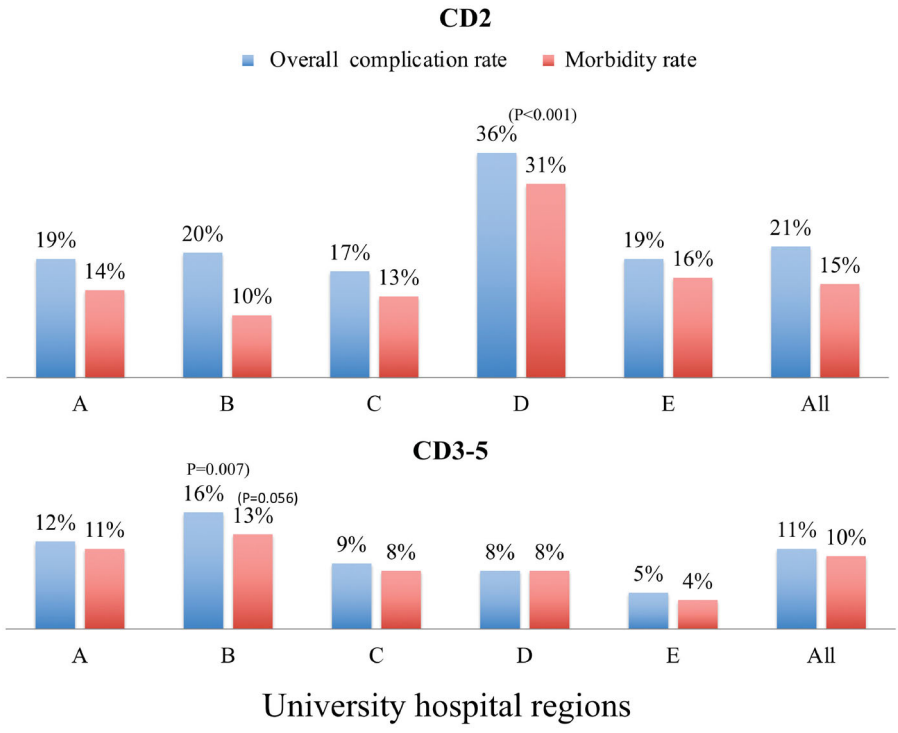

Figure 2. Postoperative complications after renal tumor surgery stratified by Clavien-Dindo (CD) grade 2 and 3–5 are presented as overall complication rates (blue) and morbidity rate (red).

(0.7%) patients died during the 90-day period after surgery. A summary list of typical complications by CD grade after kidney tumor surgery is presented in Supplementary Table S2. The numbers of complications recorded per patient was one after 303, two after 64, and three after 23 operations. Time from surgery to occurrence of complication was available for 458 of 500 complications. A total of 22 (5%) of 458 complications occurred during 31–90 days after the surgery but 45% of them (10/22) were CD3–5, including complications such as myocardial infarction, pulmonary embolism, hydronephrosis, pseudoaneurysm, ileus, urinoma and hernia.

Complications based on CD2–5

We considered the primary CD1 data to be too inconsistent, therefore, the CD1 category was excluded from the final comparative outcome analysis of 322 operations with 269 CD2 and 140 CD3–5 complications. Postoperative complications as expressed as morbidity rate was 6% lower than the overall complication rate (Figure 2). The overall rate and the morbidity rate of region D were significantly ($p < 0.001$) higher compared to the other regions. This difference was caused by CD2 complications that were statistically ($p < 0.001$) more frequent in region D. More specifically, cardiovascular and pulmonary complications together accounted for 44% of CD2 complications (23/52) in region D compared to 23% (50/217, $p < 0.001$) in the other regions combined. The overall complication rate for the more severe complications of CD3–5 was statistically significantly ($p = 0.007$) higher in region B compared to the other regions but the difference in morbidity rate was not statistically significant ($p = 0.056$). Bleedings caused a higher portion of CD3–5 complications in region B (43%, 15/35) compared to the other regions combined (30%, 31/105), but the difference was not statistically significant ($p = 0.146$).

Risk factors of Clavien-Dindo 2–5 complications

Associations between the clinical variables and morbidity of CD2–5 complications are shown in Table 3. Multivariable

Table 3. Morbidity based on Clavien-Dindo 2–5 complications by clinical variables in 1,286 patients undergoing kidney tumor surgery.

	Morbidity of CD2–5 complications, *n* (%)		
Variable	No	Yes	*p*-value
University hospital region			0.001
A	440 (75)	145 (25)	
B	164 (77)	49 (23)	
C	163 (78)	45 (22)	
D	86 (61)	55 (39)	
E	111 (80)	28 (20)	
Age			0.279
18–50 years	95 (74)	33 (26)	
51–70 years	533 (77)	162 (23)	
71+ years	336 (73)	127 (27)	
Sex			0.014
Female	407 (79)	111 (21)	
Male	557 (73)	211 (27)	
ASA			0.001
0–1	469 (79)	122 (21)	
≥ 2	495 (71)	200 (29)	
CCI score			0.007
0–1	737 (77)	222 (23)	
≥ 2	227 (69)	100 (31)	
GFR			0.468
≥ 90	223 (77)	67 (23)	
≥ 60–< 90	529 (75)	177 (25)	
< 60	205 (72)	78 (28)	
Missing data, *n*	7		
BMI			0.002
< 27	487 79)	131 (21)	
≥ 27	473 (71)	191 (29)	
Missing data, *n*	4		
ECOG			<0.001
0	467 (81)	110 (19)	
1	335 (70)	144 (30)	
≥ 2	123 (71)	50 (29)	
Missing data, *n*	39	18	
Tumor size (cm)			0.206
≤ 4	446 (73)	163 (27)	
> 4–≤ 7	263 (78)	76 (22)	
> 7	247 (75)	81 (25)	
Missing data, *n*	8	2	
Nephrectomy			0.001
Radical	600 (78)	167 (22)	
Partial	364 (70)	155 (30)	
Surgical modality			<0.001
Open	428 (69)	191 (31)	
Laparoscopy	436 (80)	107 (20)	
Robot-assisted	100 (81)	24 (19)	
Surgical approach			0.005
Transperitoneal	756 (76)	233 (24)	
Extraperitoneal	175 (68)	83 (32)	
Missing data, *n*	33	6	

Morbidity of CD2-5 is defined as number of patients suffering any CD2–5 complications.
CD, Clavien-Dindo; CCI, Charlson Comorbidity Index; ECOG, Eastern Co-operative Oncology Group; ASA, American Society of Anesthesiologists.

logistic analysis revealed that university hospital region D, male sex, BMI ≥ 27, ECOG ≥ 1, partial nephrectomy and open surgery had significantly increased risk of CD2–5 complications (Table 4).

Discussion

We found that overall complication rates in the primary uncorrected CD data ranged from 32–62% between the five university hospital regions. The similar healthcare structure of these regions with one tertiary-care university hospital should, ceteris paribus, provide about equal surgical quality.

Table 4. Multivariable logistic regression model to predict morbidity based on Clavien-Dindo 2–5 complications.

Variable	OR (95% CI)	*p*-value
University hospital region		
A	Ref.	
B	0.86 (0.58–1.29)	0.47
C	1.01 (0.66–1.53)	0.99
D	1.83 (1.16–2.87)	0.009
E	0.98 (0.61–1.60)	0.95
Sex		
Female	Ref.	
Male	1.47 (1.10–1.95)	0.008
ECOG		
0	Ref.	
1	1.65 (1.21–2.26)	0.002
2–4	1.64 (1.06–2.53)	0.026
CCI		
0–1	Ref.	
≥ 2	1.38 (1.00–1.89)	0.050
BMI		
< 27	Ref.	
≥ 27	1.56 (1.18–2.05)	0.002
Nephrectomy		
Radical	Ref.	
Partial	1.74 (1.29–2.35)	< 0.001
Surgical mode		
Open	Ref.	
Laparoscopy	0.51 (0.38–0.70)	< 0.001
Robot-assisted	0.35 (0.21–0.60)	< 0.001

Morbidity is defined as number of patients suffering any Clavien-Dindo 2–5 complications.
OR, Odds ratio; ECOG, Eastern Co-operative Oncology Group; CCI, Charlson Comorbidity Index.

The observed variation in the complication rates were greater than that expected by the authors, indicating that factors other than surgical performance and case mix could impact the results. The most important source of variation was CD1, in which 54% of assignments required correction.

It is easy to understand that primary assignments of CD1 are associated with much of the variation. This category includes a diverse collection of mild adverse effects, many of which are associated with comorbidities and many that represented just 'something less than CD2'. In addition, CD1 complications can be considered of minor clinical importance when associated with major oncological surgery. In our data, urinary retention, prolonged hospital-stay and wound problems caused most of the CD1 complications. In the final data, we did not assign a prolonged hospital stay per se as a CD complication [3]. In the central review, the variation of CD1 was markedly decreased.

CD2 complications are mostly managed with special medication such as antibiotics or blood transfusions that may be more objective criteria for retrospective evaluation. However, CD2 was the second most important category for the variation in complication rates between the five university regions. Interestingly, the most frequent pathologies associated with the high CD2 variation in region D were pulmonary and cardiovascular. While respiratory infections in general are more frequent in north compared to south Finland, it is more probable that the higher number of complications in this region were captured as a result of greater training with the CD system. The high CD3–5 complication rate in region B can be explained by a high rate of serious bleeding noted in that region.

Few studies have evaluated the consistency of the CD system in urology, which is why our study focused on it. de la Rosette et al. [11] presented 70 clinical case summaries of PCNL to 74 urologists for assigning CD grades. The overall agreement between raters in their study was only moderate ($k = 0.46$) and poor agreement was found for categories CD0 ($k = 0.30$) and CD1 ($k = 0.36$). Those authors concluded that urologists tend to have a lower agreement for grading minor complications than for severe complications and that the CD system is therefore better suited to the assessment of more serious complications in urology. The moderate inter-rater agreement of CD was also recently reported by Mitropoulos et al. [10]. In line with these conclusions, some authors who report on the outcome of renal tumor surgery already exclude CD categories 1–2 and include only categories 3–5 [16,17]. In addition, two recent studies on partial nephrectomy evaluated only CD categories 2–5 and excluded CD1 [18,19]. Our study used a different methodological approach, which also confirmed the high variability of primary CD1 assignments. Our results indicate that central review and concentrating on CD2–5 categories may improve the consistency of complication reporting on kidney tumor surgery. Having a central review might lead to more uniform reporting of complications and would also serve as a double-check. In our experience, a central review of CD data was very useful and is recommended.

It is generally acknowledged that recording by surgeons may lead to under-reporting [16]. We, however, found relatively high rates of overall complications reported in our data, especially for the CD1–2 categories. Many high-quality registries use professional data managers to carry out data collecting [20], but this, of course, requires human resources and associated increased costs. Training and education of any personnel in charge of data recording and grading of complications is therefore highly recommended, since it can prevent errors. Perhaps drawing up disease-specific and detailed guidelines for grading postoperative CD complications could make better use of the CD and diminish the need for interpretation. Interestingly, Gandaglia et al. [21] recently showed that the rate of postoperative complications was significantly increased when patients were interviewed at 30 days after the operation compared to the traditional retrospective chart review conducted over the time spent in hospital. In our data, only 5% of complications happened during the 31–90-day period after the operation, but 45% of them were CD3–5. The reason for severe complications occurring this late might be related to an inability to diagnose them in the early phase when the complications were gradually developing. These findings suggest that 90 days could be an optimum period to cover complications after kidney tumor surgery.

The different outcome figures to express complication load may cause difficulties in interpretation and may influence the results. The overall complication rate is the total number of complications divided by the number of operations [22]. The overall complication rates easily increase to high levels because there is no weighting of individual complications for different severity. Morbidity rates based on the number of patients suffering from complications and grading with the most important complication [23] seem to be more useful for comparative purposes.

The focus of our study was not on risk factors of CD complications because that would require all the analyses and discussions to be focused on using a stratified approach to evaluate the different modes and techniques of kidney surgery. However, our data confirmed that partial nephrectomy and open surgery with clinical patient selection are associated with higher complication rates than either radical nephrectomy or minimally invasive surgery.

Acute kidney injury (AKI) is a controversial topic in relation to CD. In general surgery, AKI requiring dialysis is assigned as CD4a [3] and AKI requiring medical treatment after PCNL should be assigned as CD2 [11]. However, these rules need further adjustment in kidney tumor surgery, where some deterioration of renal function is inevitable [24]. The change in GFR associated with surgery depends on the technical success of preserving renal parenchyma [25] but is also associated with comorbidity and preoperative renal function. In line with others [5,26], AKI after a planned radical nephrectomy was regarded as a sequala, but after a partial nephrectomy AKI should be related to the expected renal function.

Our study has some strengths. The large cohort size covers patients treated surgically for kidney tumors in public hospitals nationwide in Finland. Patients were followed for 90 days to detect most of the early complications. A central review of complications, corrections to the primary data, and discussions in consensus meetings helped to identify the challenging CD assignments. To the best of our knowledge, the impact of having a central review on complication rates, systematic comparison of different outcome measures for postoperative complications and the detailed timing of complications has hitherto not been reported.

The limitations of the study include the retrospective data collection and that some hospitals did not participate. More training of investigators before the study could have improved the consistency of the primary data but, at the same time, we could have lost one feature of this study. Professional data managers were not used, but could be valuable. We restricted our evaluation solely to studying postoperative complications according to CD principles but are preparing a report of intraoperative complications. Inter-rater reliability testing was not done but could have been valuable.

Conclusions

Retrospective assignments of complications for CD1 by urologists are inconsistent. A central review of the primary complications, training on CD assignment along with detailed guidelines are the necessary tools to improve consistency and these tools are recommended. Morbidity rates based on CD2–5 complications during 90 days after surgery may be optimal for quality control in kidney tumor surgery.

Disclosure statement

The authors report no conflicts of interest.

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