available at www.sciencedirect.com
journal homepage: www.europeanurology.com

European Association of Urology

Platinum Priority – Endo-urology

Editorial by Jens J. Rassweiler, Marie-Claire Rassweiler and Maurice-Stephan Michel on pp. 256–258 of this issue

Categorisation of Complications and Validation of the Clavien Score for Percutaneous Nephrolithotomy

Jean J.M.C.H. de la Rosette [a,*], ***Dedan Opondo*** [a], ***Francisco P.J. Daels*** [b], ***Guido Giusti*** [c], ***Álvaro Serrano*** [d], ***Sangam V. Kandasami*** [e], ***J. Stuart Wolf Jr.*** [f], ***Magnus Grabe*** [g], ***Stavros Gravas*** [h], ***on behalf of the CROES PCNL Study Group***

[a] *Department of Urology, AMC University Hospital, Amsterdam, The Netherlands;* [b] *Centro de Litiasis (CELIT) Hospital Italiano, Buenos Aires, Argentina;* [c] *Stone Center at Department of Urology, Istituto Clinico Humanitas, IRCCS Milan, Italy;* [d] *Department of Urology, University Hospital Guadalajara, Guadalajara, Spain;* [e] *Department of Urology, Vedanayagam Hospital and Postgraduate Institute, Tamil Nadu, India;* [f] *Department of Urology, University of Michigan Medical Center, Ann Arbor, MI, USA;* [g] *Department of Urology, Skåne University Hospital, Malmö, Sweden;* [h] *Department of Urology, University Hospital of Larissa, Larissa, Greece*

Article info

Article history:
Accepted March 27, 2012
Published online ahead of print on April 3, 2012

Keywords:
PCNL
Urinary stones
Complications
Clavien score
Urologist rating
Hospital stay
Interrater

Abstract

Background: Although widely used, the validity and reliability of the Clavien classification of postoperative complications have not been tested in urologic procedures, such as percutaneous nephrolithotomy (PCNL).
Objective: To validate the Clavien score and categorise complications of PCNL.
Design, setting, and participants: Data for 528 patients with complications after PCNL were used to create a set of 70 unique complication-management combinations. Clinical case summaries for each complication-management combination were compiled in a survey distributed to 98 urologists, who rated each combination using the Clavien classification.
Outcome measurements and statistical analysis: Interrater agreement for Clavien scores was estimated using Fleiss' kappa (κ). The relationship between Clavien score and the duration of postoperative hospital stay was analysed using multivariate nonlinear regression models that adjusted for operating time, preoperative urine microbial culture, presence of staghorn stone, and use of postoperative nephrostomy tube.
Results and limitations: Overall interrater agreement in grading postoperative complications was moderate ($\kappa = 0.457$; $p < 0.001$). Agreement was highest for Clavien score 5 and decreased with lower Clavien scores. Higher agreement was found for Clavien scores 3 and 4 than in subcategories of these scores. Postoperative stay increased with higher Clavien scores and was unaffected by inherent differences between study centres. A standard list of post-PCNL complications and their corresponding Clavien scores was created.
Conclusions: Although the Clavien classification demonstrates high validity, interrater reliability is low for minor complications. To improve the reliability and consistency of reporting adverse outcomes of PCNL, we have assigned Clavien scores to complications of PCNL.

* Corresponding author. Department of Urology, AMC University Hospital, Meibergdreef 9, 1105 AZ Amsterdam Z-O, The Netherlands. Tel. +31 20 5666030; Fax: +31 20 5669585.
E-mail address: J.J.delaRosette@amc.uva.nl (J.J.M.C.H. de la Rosette).

1. Introduction

Improvement of surgical care demands transparent, consistent, and accurate reporting of surgical outcomes that are evaluated and documented in a standardised manner [1–3]. The simplicity and ease of use of the Clavien-Dindo classification system (referred to in this paper, for brevity, as the Clavien system) to grade postoperative complications [4,5] has resulted in its widespread adoption in surgery, including urologic procedures [6–17]. However, the validity and reliability of the Clavien system have not been previously tested in urologic surgeries such as percutaneous nephrolithotomy (PCNL).

A European Association of Urology (EAU) guidelines panel recently published recommendations for reporting postoperative complications following urologic procedures [18]. Key recommendations to improve reporting of complications include the use of a standardised system; the Clavien-Dindo grading system was highly recommended. In addition, the provision of a table of all complications and corresponding scores or a list of the complications by score was recommended.

We evaluated the correlation of Clavien scores with the duration of postoperative stay (as a surrogate measure for the severity of complications) in patients who underwent PCNL, and we categorised complications of PCNL using the Clinical Research Office of the Endourological Society (CROES) PCNL Global Study database.

2. Patients and methods

2.1. Study design

This study included patients in the CROES PCNL Global Study [17] for whom a Clavien score, complications, and management were recorded. Patients with incomplete information were excluded. The Clavien score was based on the type of therapy required to treat the complication during hospital stay.

2.2. Clavien score reliability survey

An Internet-based study survey was compiled from cases drawn from centres that participated in the CROES PCNL Global Study. Cases were selected specifically to include the full range of possible complications of PCNL and their corresponding management, as documented in the Global Study database. For the survey, the study cases were summarised by age, sex, complication, and corresponding management, and all clinical information was removed, as illustrated in Table 1. The survey was distributed to 98 urologist investigators in the CROES PCNL Global Study. The urologists were asked to score the complication-management combination using the Clavien classification [6] and invited to comment on each case.

Survey data collected via Survey Monkey (Palo Alto, CA, USA) were used to estimate the overall interrater agreement on all cases and for each Clavien score using Fleiss' kappa (κ). Agreement levels were evaluated as poor (<0.20), fair (0.20–0.40), moderate (0.40–0.60), good (0.60–0.80), and very good (0.80–1.00).

2.3. Assessment of validity

Duration of postoperative hospital stay was used as a proxy measure of the severity of postoperative complications to assess the validity of the Clavien classification system. The mode Clavien score for each case was calculated from the survey data and then matched to individual patients in the CROES PCNL Global Study database based on the complication-intervention combination that was reported for each case. Multivariate nonlinear regression analyses were performed to explore the relationship between Clavien score categories and the duration of postoperative hospital stay.

Two regression models were created: The first model used the Clavien scores originally assigned during the CROES PCNL Global Study and the second model used the mode Clavien scores obtained from the study survey. Variables included in the final regression models were identified from a literature search of the predictors of postoperative stay in PCNL. The

Table 1 – A sample of the 70 clinical case summaries with complication-management combination that were sent to urologists in the survey*

Clavien score system								
Grade 1: Any deviation from the normal postoperative course without need for pharmacologic treatment or surgical, endoscopic, or radiologic interventions. Allowed treatments include antiemetics, antipyretics, analgesics, diuretics, electrolytes, and physiotherapy.								
Grade 2: Complication requiring pharmacologic treatment not in grade 1, blood transfusion, and total parenteral nutrition.								
Grade 3: Complication requiring surgical, endoscopic, or radiologic intervention.								
>>Grade 3A: Intervention *not under* general anaesthesia.								
>>Grade 3B: Intervention *under* general anaesthesia.								
Grade 4: Life-threatening complications requiring intermediate care/intensive care unit management.								
>>Grade 4A: Single organ dysfunction.								
>>Grade 4B: Multiorgan dysfunction.								
Grade 5: Death of patient.								
Please score the case summaries below using the Clavien score:								
15. A 35-yr-old male patient had bleeding after PCNL. This complication required renography and angioembolisation.								
None	1	2	3A	3B	4A	4B	5	I do not know
19. A 62-yr-old female patient had cardiac arrest after PCNL. This complication resulted into death.								
None	1	2	3A	3B	4A	4B	5	I do not know
22. A 46-yr-old female patient had colon perforation after PCNL. This complication required colostomy.								
None	1	2	3A	3B	4A	4B	5	I do not know
26. A 70-yr-old male patient had deranged renal function after PCNL. This complication required conservative management.								
None	1	2	3A	3B	4A	4B	5	I do not know
29. A 42-yr-old female patient had fever after PCNL. This complication required antibiotic treatment.								
None	1	2	3A	3B	4A	4B	5	I do not know

PCNL = percutaneous nephrolithotomy.
* A complete list of complications is found in Appendix 2.

Table 2 – Patient characteristics at baseline and selected operative data

Characteristic	Patients $n = 4230$
Gender, no. (%)	
Male	2402 (56.8)
Female	1828 (43.2)
Age, yr, mean (SD)	50.3 (14.3)
Diabetes mellitus, no. (%)	566 (13.4)
Staghorn stone, no. (%)	1026 (25.8)
Postoperative nephrostomy, no. (%)	3871 (91.9)
Positive urine culture, no. (%)	602 (14.5)
Operating time, mean, min (SD)	82.3 (45.6)
Length of hospital stay, d, mean (SD)	4.1 (3.3)
Complications, no. (%)	528 (12.5)
Clavien score, no. (%)	
0	3702 (87.5)
1	179 (4.2)
2	204 (4.8)
3A	93 (2.2)
3B	36 (0.9)
4A	12 (0.3)
4B	3 (0.1)
5	1 (<0.1)

final variables included in the model were selected using a backward selection algorithm that, after adjusting for the postoperative complications, selected variables with the strongest influence on postoperative stay. The final regression models contained the following factors: presence of staghorn stone, preoperative urine culture status, operating time, and the presence of nephrostomy tube postoperatively. By including the identity of the centres, the models also adjusted for systematic differences in hospital stay among the participating centres. Clavien score categories were treated as a categorical variable; postoperative stay and operating time were treated as continuous variables and modelled to account for any nonlinear relationship between these two parameters. Since we had only one patient in the cohort with a Clavien score 5, we did not include that patient in the multivariate analysis.

Text mining and statistical analysis were performed using R statistical programming software v.2.12.2. (R Project for Statistical Computing; http://www.r-project.org/).

3. Results

3.1. Patients

This study included 4230 patients from the CROES PCNL Global Study database. Patient characteristics at baseline and outcome data are shown in Table 2. A total of 528 patients (12.5%) were identified with complications reported by Clavien score. Seventy unique complication-management combinations were identified to represent each patient in this cohort.

3.2. Survey response

Complete responses were received from 74 of the 98 urologists (75.5%) in 26 countries who were invited to complete the online survey. Rates of agreement between urologists varied for grading the postoperative complications of clinical case summaries using the Clavien score. Overall agreement between urologists was moderate ($\kappa = 0.457$; $p < 0.001$). For Clavien score categories, agreement ranged from fair (Clavien score 0) ($\kappa = 0.297$; $p < 0.0001$) to very good (Clavien score 5) ($\kappa = 0.986$; $p < 0.0001$) (Fig. 1a). Agreement increased substantially when the subgroups of Clavien score 3 and 4 were merged, with κ values of 0.769 (good) and 0.810 (very good), respectively (Fig. 1b).

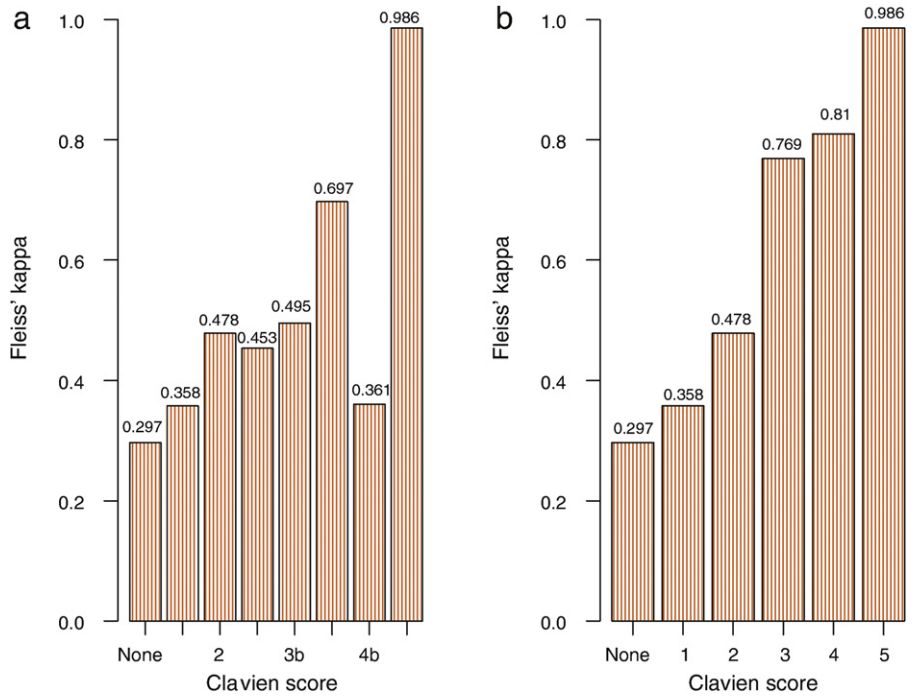

Fig. 1 – Relationship between urologists' agreement and severity of complications according (a) full and (b) contracted Clavien classification.

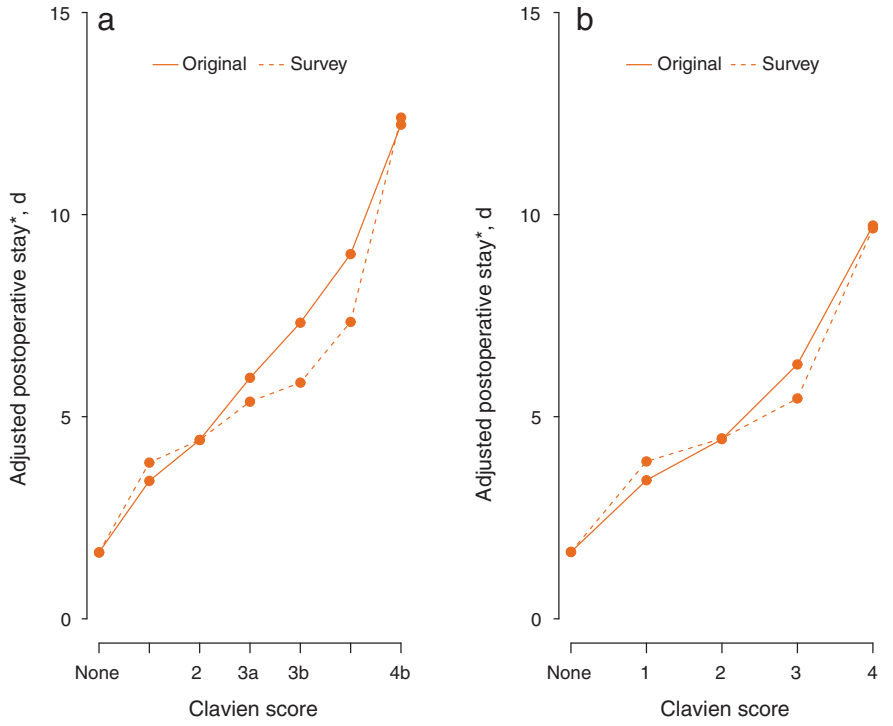

Fig. 2 – Relationship between Clavien score and postoperative hospital stay based on Clavien score originally assigned and modal Clavien score assigned during the online survey for (a) full and (b) contracted Clavien classification. Hospital stay was adjusted for study centre, preoperative urine culture, presence of nephrostomy tube postoperatively, and the presence of staghorn stone.

3.3. *Clavien score and duration of hospitalisation*

Longer postoperative stay was associated with a higher score in both the original Clavien score assigned during the Global Study and the modal survey Clavien score (Fig. 2a and 2b). The relationship remained after correcting for differences between study centres (Fig. 3a). The presence of even minor complications (Clavien score 1) had a higher

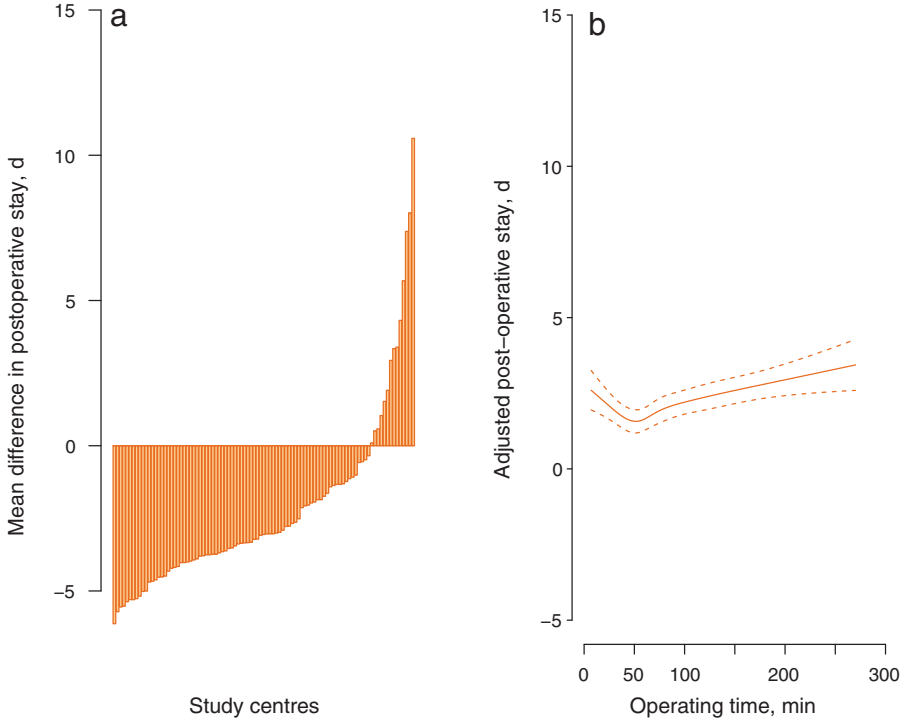

Fig. 3 – Effects of (a) study centre and (b) operating time used to adjust the multivariate nonlinear regression analysis of the relationship between Clavien score and postoperative stay.

Table 3 – Relationship between the original Clavien score and hospital stay determined by a multivariate nonlinear regression model adjusting for the presence of staghorn stones, positive preoperative urine culture, postoperative nephrostomy, duration of surgery, and centre where percutaneous nephrolithotomy was performed*

Characteristic	Effect size, d **	95% CI
Clavien score		
1	1.77	1.35–2.18
2	2.78	2.39–3.16
3A	4.31	3.77–4.85
3B	5.68	4.72–6.64
4A	7.38	5.89–8.88
4B	10.58	7.74–13.42
Staghorn stone	0.51	0.31–0.72
Postoperative nephrostomy (relative to no nephrostomy)	1.50	1.11–1.90
Positive preoperative urine culture (relative to negative culture)	0.36	0.12–0.60
Intercept†	4.68	–

CI = confidence interval.

* The regression model was adjusted for presence of staghorn stone, preoperative urine culture, postoperative nephrostomy, operating time, and for differences in mean postoperative stay between study centres (centre effect was the mean difference in hospital stay from the reference centre [the centre with the highest number of patients included in the study] and the other centres [see Fig. 3a]). Clavien score was treated as a categorical variable, and two regression models were created to account for the full Clavien classification and the contracted Clavien classification without subgroups of scores 3 and 4. Postoperative stay was treated as a continuous outcome variable. Operating time was treated as a continuous predictor variable and was modelled with natural spines with 4 degrees of freedom to explore any nonlinear relationships between operating time and duration of postoperative stay. Remaining covariates were treated as categorical variables.

** The effect size is the average number of additional days a patient requires in the hospital >4.68 d, which is the mean duration of stay of noncomplicated patient in the reference centre.

† Intercept refers to the mean hospital stay of a patient without complications and with nonstaghorn stone, no postoperative nephrostomy, and a negative urine culture.

mean effect on length of stay than other risk factors, such as presence of nephrostomy tube postoperatively, presence of staghorn stone, and positive urine cultures (Table 3). Shortest durations of hospital stay were observed for patients whose operations lasted between 50 and 75 min. Length of stay increased with a decrease in operating duration <50 min, just as with operating duration >75 min (Fig. 3b). We also observed that higher American Society of Anaesthesiologists (ASA) score was indirectly associated with longer hospital stay, because higher ASA scores resulted in more complications and high Clavien scores, which were associated with longer hospital stay.

4. Discussion

Total complication rates of up to 83% following PCNL have been reported [19], although a high proportion are clinically insignificant [20,21]. Conversely, failure to report negative postoperative events adequately or at all is not uncommon [2]. Novara et al. also observed that urologists under-reported low-grade complications after radical cystectomy [22]. Together, this emphasises the importance of grading perioperative complications accurately according to their severity. An EAU guidelines panel and others have recommended use of the Clavien classification system to standardise reporting of complications after urologic procedures, such as PCNL [18,23].

Our study shows that urologists tended to have a lower rate of agreement for grading minor complications than for severe complications. This implies that the Clavien system is better suited to the assessment of more serious complications. Interpretation of what constitutes a postoperative complication varies from one urologist to another, which makes classifying less overtly negative postoperative events more variable and may contribute to the low reliability of grading minor complications [24]. In addition, some potentially serious complications, when managed conservatively, will be classified as minor complications with Clavien scores lower than those of complications deemed less serious. This is an inherent weakness of the Clavien system, since it is purely based on the management strategy for a given complication and not the potential risk to which a patient is exposed by a complication.

We noted lower interurologist agreement for Clavien scores 3A and 3B. This suggests differences in opinion between urologists on classification of complications that require surgical or radiologic management. Similarly, agreement on single organ failure (Clavien score 4A) or multiple organ failure (Clavien score 4B) as a requirement for intensive care unit admission was also low. Such variations are more notable given that study centres were considered to have high expertise in this medical field. Notably, agreement between urologists was significantly higher without subclassification of Clavien categories 3 and 4. It has been observed that the variations in subclassification of Clavien category 3 complications may be due to differences in the management approaches chosen by different centres that treat complications [25]. For instance, reinterventions performed under general anaesthesia in one centre may be performed under local anaesthesia in another centre.

The consistent relationship found between duration of hospital stay and Clavien score confirms the validity of the Clavien classification as a measure of complication(s) severity when the duration of postoperative stay is used as a surrogate measure. This relationship remained true after correcting for the influence of study centre factors, such as local patient discharge policy or case numbers. Furthermore, the relationship remained after correcting for other factors known to be associated with prolonged postoperative stay following PCNL. In demonstrating this relationship, our study illustrates that the boundaries of complication scores described in the Dindo-Clavien system are externally valid for postoperative complications of PCNL.

The assignment of specific complications to Clavien score categories as presented here (Table 4) is intended to increase agreement of interurologist rating and improve the reliability of grading the severity of PCNL complications. High concordance should improve comparability between studies of complications and specific morbidities in PCNL.

Table 4 – Categorisation of percutaneous nephrolithotomy-specific complications according to Clavien classification score based on expert opinions collected from 74 urologists via an international survey

Clavien score	Complication-management definitions*
None	• Normal postoperative trajectory without any unexpected deviation
	• Blocked nephrostomy managed by removal of nephrostomy(without consequences)
	• Nephrostomy tube discomfort that requires removal of nephrostomy
	• Postoperative pain managed by nonopioid analgesics
1	• Postoperative pain managed by opioid with or without adjunct analgesic regimen
	• Postoperative fever (>38.0 °C) managed by observation without antibiotics
	• Deranged renal function that requires IV fluid management only
	• Bleeding managed using IV fluid without need for blood transfusion
	• Bleeding that requires a single episode of nephrostomy clamping
	• Bleeding that requires skin compression/pressure dressing
	• Renal pelvic perforation managed by watchful waiting
	• Urine leakage managed by watchful waiting
	• Ureteric clot managed by watchful waiting
	• Bladder retention without blood clot that requires bladder catheterization
	• Pneumothorax managed by watchful waiting
	• Hydrothorax managed by watchful waiting
	• Displaced nephrostomy managed by watchful waiting
	• Intestinal obstruction managed without nasogastric decompression
2	• Bleeding requiring blood transfusion
	• Nephrostomy site cellulitis managed by antibiotics
	• Symptomatic UTI managed using antibiotics
	• Postoperative fever (>38.0 °C) managed with antibiotics in the ward
	• Colon perforation managed conservatively using IV fluid and antibiotics without controlled colocutaneous fistula
	• Postoperative ileus managed by nasogastric decompression
	• Postoperative pneumonia managed by antibiotics
	• Heart failure (NYHA I and II) requiring management by medications in the ward
	• Hyposaturation managed by oxygen in the ward
	• Pulmonary oedema managed by diuretics
	• Supraventricular arrhythmias requiring antiarrhythmic medications
	• Minor atelectasis requiring medical management
3A	• Febrile UTI or suspected sepsis without organ failure requiring supportive therapy and enhanced monitoring
	• Bleeding requiring multiple bladder washouts/irrigations
	• Bleeding managed with haemostatic agents placed endoscopically
	• Bleeding that requires multiple episodes of nephrostomy clamping (>4 h apart)
	• Bleeding managed by postoperative ureteric stenting without general anaesthesia
	• Bleeding managed by postoperative placement of new larger-bore nephrostomy tamponade
	• Colon perforation managed conservatively using controlled colocutaneous fistula
	• Hemothorax managed by intercostal draining under local anaesthesia
	• Hydrothorax managed by intercostal draining under local anaesthesia
	• Pneumothorax managed by intercostal draining under local anaesthesia
	• Renal pelvic perforation managed by prolonged nephrostomy tube or postoperative placement of nephrostomy
	• Renal pelvic perforation managed by ureteric stenting without general anaesthesia
	• Ureteric clot obstruction managed by ureteric stenting without general anaesthesia
	• Urine leakage managed by postoperative placement of a new nephrostomy tube
	• Urine leakage managed by ureteric stenting without general anaesthesia
	• Blocked nephrostomy managed by ureteric stenting without general anaesthesia
	• Misplaced double-J stent managed by repositioning
	• Displaced nephrostomy requiring ureteric stenting without general anaesthesia
	• Perirenal abscess managed by percutaneous drainage
3B	• Bleeding managed by angioembolisation
	• Bleeding managed by nephrectomy
	• Colon perforation managed by colostomy
	• Ureteric stricture managed by balloon dilation
	• Avulsion of the ureteropelvic junction managed by surgical repair
	• Retained nephrostomy requiring removal under anaesthesia
	• Intestinal obstruction managed by gastrostomy
	• Perirenal abscess managed by open drainage
4A	• Bleeding (hypovolaemic shock) requiring ICU management
	• Adult respiratory distress syndrome requiring ICU management
	• Hyposaturation requiring ICU management
	• Pulmonary oedema requiring ICU management
	• Heart failure requiring ICU management
	• Hypothermia requiring ICU management
	• Acute renal failure requiring ICU management
	• Arrhythmias with haemodynamic instability requiring ICU management
	• Severe atelectasis requiring intubation and requiring ICU management
4B	• Urosepsis with multiple organ failure requiring ICU management
5	• Any complication leading to death

IV = intravenous; UTI = urinary tract infection; NYHA = New York Heart Association; ICU = intensive care unit.

In addition, we observe that the Dindo-Clavien classification of surgical complications is focused on surgical complications requiring or not requiring an intervention. However, infectious complications are frequent in endourologic procedures such as PCNL [26]. The severity of these infections ranges from simple bacteriuria to severe sepsis with multiple organ failure [27]. Classifying the infectious complications in the different categories is difficult. A transitory, untreated, asymptomatic bacteriuria can be considered as a noncomplication. A short, transitory, postoperative fever without any other symptoms of systemic inflammatory response and not treated with antibiotics can obviously be classified as a score 1, while sepsis with organ failure requiring intensive care management is classed as a score 4. In addition, a febrile urinary tract infection treated with antibiotics is suggested as a score 2. Clinical experience shows, however, that patients showing early signs of sepsis without established circulatory failure [26], but requiring intensive antibiotic treatment and fluid supportive therapy with an intermediate level of care monitoring, are not classifiable in the Clavien category 3 they merit placing in. This weakness should eventually be addressed.

We acknowledge that the Clavien scoring system does not incorporate imaging, which can have an important role in the diagnosis of post-PCNL complications [28]. Seminis et al. demonstrated in a multicentre study that computed tomography imaging detected more complications after PCNL [28]. Higher detection rates of complications, which would otherwise go undetected, lead to more interventions, which result in higher Clavien scores. The Clavien classification also does not incorporate a measure of the impact of preoperative health status on the morbidity outcomes of PCNL.

Although we used duration of postoperative stay as a surrogate measure of the severity of complications and further adjusted for variations between participating centres, we remain cognizant of the inherent differences in hospital stay between centres due to local policies and practice.

Follow-up studies are needed to investigate whether the assignment of specific complications to Clavien score categories and combining Clavien subcategories 3A with 3B and 4A with 4B would improve the reliability of the scoring system.

5. Conclusions

Although the Clavien score demonstrates high validity for the impact of PCNL complication on duration of stay, its interrater reliability is low for minor complications. We have assigned complications to Clavien score categories to standardise and improve the reliability of reporting of adverse outcomes of PCNL.

Author contributions: Jean de la Rosette 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: De la Rosette, Opondo.
Acquisition of data: De la Rosette, Opondo, Daels, Giusti, Serrano, Kandasami, Wolf, Grabe, Gravas.
Analysis and interpretation of data: De la Rosette, Opondo, Daels, Giusti, Serrano, Kandasami, Wolf, Grabe, Gravas.
Drafting of the manuscript: De la Rosette, Opondo.
Critical revision of the manuscript for important intellectual content: De la Rosette, Opondo, Daels, Giusti, Serrano, Kandasami, Wolf, Grabe, Gravas.
Statistical analysis: Opondo.
Obtaining funding: De la Rosette, Opondo, Daels, Giusti, Serrano, Kandasami, Wolf, Grabe, Gravas.
Administrative, technical, or material support: De la Rosette, Opondo.
Supervision: De la Rosette.
Other (specify): None.

Financial disclosures: Jean de la Rosette certifies that all conflicts of interest, including specific financial interests and relationships and affiliations relevant to the subject matter or materials discussed in the manuscript (eg, employment/affiliation, grants or funding, consultancies, honoraria, stock ownership or options, expert testimony, royalties, or patents filed, received, or pending), are the following: None.

Funding/Support and role of the sponsor: The CROES PCNL Global Study was supported by an unrestricted educational grant from Olympus. Olympus was involved in the design and conduct of the study.

Appendix A. List of principal investigators who participated in the Clinical Research Office of the Endourological Society Percutaneous Nephrolithotomy Global Study and the survey on Clavien score reliability

First name	Last name	Country
Ad	Hendrikx	Netherlands
Ahmet	Tefekli	Turkey
Akito	Yamaguchi	Japan
Alberto	Breda	United States
Alessandro	D'Addessi	Italy
Alfonso	Crisci	Italy
Ali Riza	Kural	Turkey
Álvaro	Serrano Pascual	Spain
Andras	Hoznek	France
Andreas	Gross	Germany
Andreas	Skolarikos	Greece
Anthony	Timoney	United Kingdom
Antonello	De Lisa	Italy
Antonio	Celia	Italy
Antonio	Frattini	Italy
Arthur	Smith	United States
Arup	Mandal	India
Augusto	Rippa	Italy
Ben	van Cleynenbreugel	Belgium
Benjamin	Silva	Chile
Bulent	Onal	Turkey
Burak	Turna	Turkey
Carson	Wong	United States
Christian	Saussine	France
Christoph	Klingler	Austria
Dalibor	Pacik	Czech Rep
Damien	Bolton	Australia
David	Tolley	United Kingdom
Dean	Assimos	United States
Emanuele	Montanari	Italy
Evangelos	Liatsikos	Greece
Francisco Pedro Juan	Daels	Argentina
Furio	Cauda	Italy
Ganesh	Gopalakrishnan	India
Gaspar	Ibarlucea Gonzalez	Spain
Gaston	Labate	Argentina
Giampaolo	Bianchi	Italy
Glenn	Preminger	United States
Gonzalo	Bueno Chomon	Spain

Appendix A (*Continued*)

First name	Last name	Country
Guido	Guisti	Italy
Hassan	Razvi	Canada
Helena	Walfridsson	Sweden
Hemendra	Shah	India
James	Lingeman	United States
Jan	Kums	Netherlands
Jean	de la Rosette	Netherlands
Jens	Rassweiler	Germany
Jens-Uwe	Stolzenburg	Germany
Jorge	Gutierrez	Mexico
Jorge	Rioja	Spain
José	Amón Sesmero	Spain
Jose Gabriel	Valdivia Uria	Spain
Juan Antonio	Lopez Garcia	Spain
Kandasami	Sangam	India
Kikuo	Nutahara	Japan
Kittinut	Kijvikai	Thailand
Konrad	Szymanski	Canada
Lei	Shi	China
Luigi	Cormio	Italy
Magnus	Grabe	Sweden
Mahesh	Desai	India
Tome	Lopes	Portugal
Marco	De Sio	Italy
Marco	Garofalo	Italy
Margaret	Pearle	United States
Mario	Sofer	Israel
Michael	Grasso	United States
Michael	Louie	United States
Michael	Luke	Denmark
Michael	Melekos	Greece

Appendix A (*Continued*)

First name	Last name	Country
Mihail Radu	Boja	Romania
Mircea	Botoca	Romania
Mordechai	Duvdevani	Israel
Narmada	Gupta	India
Noor	Buchholz	United Kingdom
Palle	Osther	Denmark
Peter	Alken	Germany
Peter	Olbert	Germany
Peter	Vijverberg	Netherlands
Petrisor	Geavlete	Romania
Pietro	Saba	Italy
Rakesh	Kapoor	India
Ramakrishna	Venkatesh	United States
Robert	Nadler	United States
Roberto	Scarpa	Italy
Selcuk*	Guven	Turkey
S.K.	Pal	India
Stavros*	Gravas	Greece
Stephen	Nakada	United States
Stuart	Wolf, Jr	United States
Tibet	Erdogru	Turkey
Timothy	Averch	United States
Viorel	Bucuras	Romania
Wei	Xue	China
Willem	Boellaard	Netherlands
Willem	Strijbos	Netherlands
Xiaochun	Zhang	China
Yinghao	Sun	China

* Additional investigator included in the survey.

Appendix B. List of clinical case summaries used in a global survey for assessing reliability of the Clavien score system for percutaneous nephrolithotomy

	Description of complication-management combinations
1	A 67-yr-old female patient had acute renal failure after PCNL. This complication required bicarbonate supplementation.
2	An 83-yr-old female patient had acute respiratory distress syndrome after PCNL. This complication required intensive care management.
3	A 67-yr-old male patient had arrhythmias after PCNL. This complication required antiarrhythmics.
4	A 33-yr-old female patient had atelectasis after PCNL. This complication required antiasthma treatment.
5	A 26-yr-old female patient had avulsed uteropelvic junction after PCNL. This complication required open surgical repair.
6	A 76-yr-old male patient had bladder urine retention after PCNL. This complication required bladder catheterisation.
7	A 43-yr-old female patient had bleeding after PCNL. This complication required bladder washout.
8	A 19-yr-old male patient had bleeding after PCNL. This complication required blood transfusion.
9	A 58-yr-old female patient had bleeding after PCNL. This complication required clamping nephrostomy.
10	A 42-yr-old female patient had bleeding after PCNL. This complication required conservative management.
11	A 60-yr-old male patient had bleeding after PCNL. This complication required a haemostatic agent.
12	A 73-yr-old male patient had bleeding after PCNL. This complication required intensive care management.
13	A 53-yr-old female patient had bleeding after PCNL. This complication required large-bore nephrostomy tamponade.
14	A 61-yr-old male patient had bleeding after PCNL. This complication required local skin compression.
15	A 35-yr-old male patient had bleeding after PCNL. This complication required renography and angioembolisation.
16	A 54-yr-old female patient had bleeding after PCNL. This complication required ureteric stenting.
17	A 60-yr-old female patient had blocked nephrostomy after PCNL. This complication required removal of nephrostomy.
18	A 29-yr-old female patient had blocked nephrostomy after PCNL. This complication required ureteric stenting.
19	A 62-yr-old female patient had cardiac arrest after PCNL. This complication resulted in death.
20	A 54-yr-old male patient had cellulitis at nephrostomy site after PCNL. This complication required antibiotic treatment.
21	A 70-yr-old female patient had chest pain after PCNL. This complication required nitroglycerine.
22	A 46-yr-old female patient had colon perforation after PCNL. This complication required colostomy.
23	A 61-yr-old female patient had colon perforation after PCNL. This complication required conservative management.
24	A 61-yr-old female patient had corneal abrasion after PCNL. This complication required referral to an ophthalmologist.
25	A 55-yr-old female patient had delirium after PCNL. This complication required electrolyte correction and naloxone treatment.
26	A 70-yr-old male patient had deranged renal function after PCNL. This complication required conservative management.
27	A 72-yr-old male patient had displaced nephrostomy after PCNL. This complication required conservative management.
28	A 74-yr-old female patient had displaced nephrostomy after PCNL. This complication required ureteric stenting.
29	A 42-yr-old female patient had fever after PCNL. This complication required antibiotic treatment.
30	A 40-yr-old female patient had fever after PCNL. This complication required conservative management.
31	A 56-yr-old female patient had heart failure after PCNL. This complication required intensive care management.

Appendix B (*Continued*)

	Description of complication-management combinations
32	A 42-yr-old male patient had heart failure after PCNL. This complication required medical treatment.
33	A 45-yr-old male patient had haemothorax after PCNL. This complication required an intercostal drain.
34	A 44-yr-old male patient had hydrothorax after PCNL. This complication required conservative management.
35	A 54-yr-old female patient had hydrothorax after PCNL. This complication required an intercostal drain.
36	A 63-yr-old male patient had hyperglycaemia after PCNL. This complication required insulin treatment.
37	A 63-yr-old female patient had hypoglycaemia after PCNL. This complication required glucose infusion.
38	A 44-yr-old male patient had hypokalaemia after PCNL. This complication required intravenous potassium.
39	A 71-yr-old female patient had hyposaturation after PCNL. This complication required intensive care management.
40	A 46-yr-old female patient had hyposaturation after PCNL. This complication required oxygen therapy.
41	A 58-yr-old male patient had hypothermia after PCNL. This complication required intensive care management.
42	A 43-yr-old male patient had intestinal obstruction after PCNL. This complication required conservative management.
43	A 72-yr-old male patient had intestinal obstruction after PCNL. This complication required gastrostomy.
44	A 46-yr-old male patient had misplaced double J stent after PCNL. This complication required repositioning the double J stent.
45	A 63-yr-old female patient had no complication after PCNL.
46	A 40-yr-old male patient had nephrostomy discomfort after PCNL. This complication required removing the nephrostomy.
47	A 66-yr-old male patient had pain after PCNL. This complication required analgesics.
48	A 59-yr-old male patient had pelvic perforation after PCNL. This complication required conservative management.
49	A 23-yr-old male patient had pelvic perforation after PCNL. This complication required nephrostomy.
50	A 36-yr-old male patient had pelvic perforation after PCNL. This complication required ureteric stenting.
51	A 62-yr-old female patient had perirenal abscess after PCNL. This complication required abscess drainage.
52	A 66-yr-old female patient had pneumonia after PCNL. This complication required antibiotic treatment.
53	A 32-yr-old female patient had pneumothorax after PCNL. This complication required conservative management.
54	A 42-yr-old female patient had pneumothorax after PCNL. This complication required an intercostal drain.
55	A 64-yr-old female patient had pulmonary oedema after PCNL. This complication required diuretic treatment.
56	A 57-yr-old male patient had pulmonary oedema after PCNL. This complication required intensive care management
57	A 51-yr-old male patient had respiratory acidosis after PCNL. This complication required oxygen therapy.
58	A 42-yr-old male patient had a retained nephrostomy tube after PCNL. This complication required extraction in ward.
59	A 38-yr-old male patient had retained nephrostomy tube after PCNL. This complication required ureteroscopic removal
60	A 55-yr-old male patient had septic shock after PCNL. This complication required intensive care management.
61	A 59-yr-old male patient had thromboembolism after PCNL. This complication required anticoagulation.
62	A 66-yr-old male patient had an unknown complication after PCNL. Type of management required for this complication is unknown.
63	An 80-yr-old male patient had ureteric clot obstruction after PCNL. This complication required conservative management.
64	A 56-yr-old male patient had ureteric clot obstruction after PCNL. This complication required ureteric stenting.
65	A 47-yr-old male patient had ureteric stricture after PCNL. This complication required balloon dilation.
66	A 61-yr-old female patient had urine leakage and/or urinoma after PCNL. This complication required conservative management.
67	A 56-yr-old female patient had urine leakage and/or urinoma after PCNL. This complication required nephrostomy.
68	A 48-yr-old female patient had urine leakage and/or urinoma after PCNL. This complication required ureteric stenting.
69	A 68-yr-old male patient had urosepsis after PCNL. This complication required antibiotic treatment.
70	A 45-yr-old female patient had vomiting after PCNL. This complication required antiemetics and intravenous fluids.

PCNL = percutaneous nephrolithotomy.

References

[1] Dindo D, Clavien PA. Quality assessment in surgery: mission impossible? Patient Saf Surg 2010;4:18.

[2] Breau RH, Gaboury I, Scales Jr CD, Fesperman SF, Watterson JD, Dahm P. Reporting of harm in randomized controlled trials published in the urological literature. J Urol 2010;183:1693–7.

[3] Krupski TL. Standardization of reporting surgical complications—are we ready? J Urol 2010;183:1671–2.

[4] Clavien PA, Sanabria JR, Strasberg SM. Proposed classification of complications of surgery with examples of utility in cholecystectomy. Surgery 1992;111:518–26.

[5] Dindo D, Demartines N, Clavien PA. Classification of surgical complications: a new proposal with evaluation in a cohort of 6336 patients and results of a survey. Ann Surg 2004;240:205–13.

[6] Stolzenburg JU, Rabenalt R, Do M, et al. Categorisation of complications of endoscopic extraperitoneal and laparoscopic transperitoneal radical prostatectomy. World J Urol 2006;24:88–93.

[7] Permpongkosol S, Link RE, Su LM, et al. Complications of 2,775 urological laparoscopic procedures: 1993 to 2005. J Urol 2007;177:580–5.

[8] De la Rosette JJ, Zuazu JR, Tsakiris P, et al. Prognostic factors and percutaneous nephrolithotomy morbidity: a multivariate analysis of a contemporary series using the Clavien classification. J Urol 2008;180:2489–93.

[9] Tefekli A, Ali Karadag M, Tepeler K, et al. Classification of percutaneous nephrolithotomy complications using the modified Clavien grading system: looking for a standard. Eur Urol 2008;53:184–90.

[10] Constantinides CA, Tyritzis SI, Skolarikos A, Liatsikos E, Zervas A, Deliveliotis C. Short- and long-term complications of open radical prostatectomy according to the Clavien classification system. BJU Int 2009;103:336–40.

[11] Harper JD, Breda A, Leppert JT, Veale JL, Gritsch HA, Schulam PG. Experience with 750 consecutive laparoscopic donor nephrectomies–is it time to use a standardized classification of complications? J Urol 2010;183:1941–6.

[12] Novara G, Ficarra V, D'Elia C, Secco S, Cavalleri S, Artibani W. Prospective evaluation with standardised criteria for postoperative complications after robotic-assisted laparoscopic radical prostatectomy. Eur Urol 2010;57:363–70.

[13] Rabbani F, Yunis LH, Pinochet R, et al. Comprehensive standardized report of complications of retropubic and laparoscopic radical prostatectomy. Eur Urol 2010;57:371–86.

[14] Rioja Zuazu J, Hruza M, Rassweiler JJ, de la Rosette JJ. The Clavien classification system to optimize the documentation of PCNL morbidity. Arch Ital Urol Androl 2010;82:20–2.

[15] Lebeau T, Roupret M, Ferhi K, et al. Assessing the complications of laparoscopic robot-assisted surgery: the case of radical prostatectomy. Surg Endosc 2010;25:536–42.
[16] Özden E, Mercimek MN, Yakupoğlu YK, Özkaya O, Sarikaya Ş. Modified Clavien classification in percutaneous nephrolithotomy: assessment of complications in children. J Urol 2011;185:264–8.
[17] De la Rosette J, Assimos D, Desai M, et al. The Clinical Research Office of the Endourological Society Percutaneous Nephrolithotomy Global Study: indications, complications, and outcomes in 5803 patients. J Endourol 2011;25:11–7.
[18] Mitropoulos D, Artibarni W, Graefen M, Remzi M, Rouprêt M, Truss M. Reporting and grading of complications after urologic surgical procedures: an ad hoc EAU Guidelines Panel assessment and recommendations. Eur Urol 2012;61:341–9.
[19] Michel MS, Trojan L, Rassweiler JJ. Complications in percutaneous nephrolithotomy. Eur Urol 2007;51:899–906.
[20] Lewis S, Patel U. Major complications after percutaneous nephrostomy-lessons from a department audit. Clin Radiol 2004; 59:171–9.
[21] Labate G, Modi P, Timoney A, et al. The percutaneous nephrolithotomy global study: classification of complications. J Endourol 2011; 25:1275–80.
[22] Novara G, De Marco V, Aragona M, et al. Complications and mortality after radical cystectomy for bladder transitional cell cancer. J Urol 2009;182:914–21.
[23] Seitz C, Desai M, Häcker A, et al. Incidence, prevention, and management of complications following percutaneous nephrolitholapaxy. Eur Urol 2012;61:146–58.
[24] Dindo D, Clavien PA. What is a surgical complication? World J Surg 2008;32:939–41.
[25] Hruza M, Weiss HO, Pini G, et al. Complications in 2200 consecutive laparoscopic radical prostatectomies: standardised evaluation and analysis of learning curves. Eur Urol 2010;58:733–41.
[26] Mariappan P, Smith G, Bariol SV, Moussa SA, Tolley DA. Stone and pelvic urine culture and sensitivity are better than bladder urine as predictors of urosepsis following percutaneous nephrolithotomy: a prospective clinical study. J Urol 2005;173:1610–4.
[27] Grabe M, Bjerklund-Johansen TE, Botto H, et al. Guidelines on urological infections. Arnhem, The Netherlands: European Association of Urology; 2011. http://www.uroweb.org/gls/pdf/15_Urological_Infections.pdf.
[28] Semins MJ, Bartik L, Chew BH, et al. Multicenter analysis of postoperative CT findings after percutaneous nephrolithotomy: defining complication rates. Urology 2011;78:291–4.