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The Anniversary Study – 20 years of Clavien-Dindo Classification & 10 years of Comprehensive Complication Index®

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ABSTRACT

Outcome reporting of surgical procedures was revolutionized in 2004 with the introduction of the Clavien-Dindo (CD) classification.[1] This 5-scale grading system offers an objective, simple, reliable, and reproducible way of recording complications, and has gained wide acceptance among the international surgical community. With over 27'000 citations the original paper has become the most cited article in the surgical literature.

In 2013, another milestone in surgical outcome reporting was introduced, the Comprehensive Complication Index (CCI®).[2] The CCI® is based on the Clavien-Dindo system and is the first metric, which captures the entire postoperative morbidity as a numeric scale from 0-100 from the day of surgery until most complications are expected to have occurred or beyond.

Both systems have gained wide acceptance and are routinely used in many centers. However, users have been challenged with many questions over the years mostly on how to rank some postoperative events.

Now, after 20 and 10 years of working with these two well established outcome reporting systems, it is time for a critical evaluation.

MATERIALS

International Survey on limesurvey

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Introduction

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	A	B
	Title	Anniversary Study – 20 years of Clavien-Dindo Classification & 10 years of Comprehensive Complication Index®
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Background

2 Outcome reporting of surgical procedures was revolutionized in 2004 with the introduction of the Clavien-Dindo (CD) classification.[1] This 5-scale grading system offers an objective, simple, reliable, and reproducible way of recording complications, and has gained wide acceptance among the international surgical community. With over 27'000 citations the original paper has become the most cited article in the surgical literature.

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Now, after 20 and 10 years of working with these two well established outcome reporting systems, it is time for a critical evaluation.

Aim

3 Firstly, we would like to answer the following research questions:

Question 1: How many randomized controlled trials (RCTs) assessing surgical and other invasive interventions used the CD classification or the CCI® as primary, secondary, or exploratory endpoint?

Question 2: How has the use of the CD classification and CCI® developed over time?

Question 3: How many of those RCTs used a modified classifications and what were the modifications?

Further, this study is intended to provide some guidance for the application of the CD classification and the CCI® to achieve consistency of application for both classifications.

Finally, based on the study results, we will consider whether adjustments of the CD classification and/or CCI® are necessary.

Methods

4.1 Protocol registration

Protocol is in line with international ethical parameters and as it is a study with secondary data, there is no need to seek approval from a research ethics committee according to the law for human research in Switzerland.
The protocol will be published on https://www.protocols.io

4.2 Analysis of the Literature

A literature search will be conducted to answer the above-mentioned research question 1 to 3.

- Selection criteria:
  We will include only randomized controlled trials.
- Inclusion criteria:
  Trials using the CD classification or the CCI® as an endpoint.
- Search strategy:
  We will use Scopus, an Elsevier's abstract and citation database, to find all articles that cite one of the following papers:
  - 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[1]
  - Clavien PA, Barkun J, de Oliveira ML et al. The Clavien-Dindo classification of surgical complications: five-year experience. Ann Surg 2009.[3]
  - Slankamenac K, Graf R, Barkun J et al. The comprehensive complication index: a novel continuous scale to measure surgical morbidity. Ann Surg 2013.[2]
  - o Clavien PA, Vetter D, Staiger RD et al. The Comprehensive Complication Index (CCI®): Added Value and Clinical Perspectives 3 Years "Down the Line". Ann Surg[4]

Then we will run an RCT filter over the results. We will use the Filter developed by the National University of Singapore (NUS) Medical Library:
(INDEXTERMS ("clinical trials" OR "clinical trials as a topic" OR "randomized controlled trial" OR "Randomized Controlled Trials as Topic" OR "controlled clinical trial" OR "Controlled Clinical Trials" OR "random allocation" OR "Double-Blind Method" OR "Single-Blind Method" OR "Cross-Over Studies" OR "Placebos" OR "multicenter study" OR "double blind procedure" OR "single blind procedure" OR "crossover procedure" OR "clinical trial" OR "controlled study" OR "randomization" OR "placebo")) OR (TITLE-ABS-KEY (("clinical trials" OR "clinical trials as a topic" OR "randomized controlled trial" OR "Randomized Controlled Trials as Topic" OR "controlled clinical trial" OR "Controlled Clinical Trials as Topic" OR "random allocation" OR "randomly allocated" OR "allocated randomly" OR "Double-Blind Method" OR "Single-Blind Method" OR "Cross-Over Studies" OR "Placebos" OR "cross-over trial" OR "single blind" OR "double blind" OR "factorial design" OR "factorial trial"))) OR (TITLE-ABS (clinical trial OR*

trial OR rct* OR random* OR blind*))*

The search results will then be imported into Cadima for an abstract screening to identify potentially eligible articles (randomized controlled trials which used the CD classification or the CCI® as a trial endpoint). Disagreements and uncertainties will be discussed and resolved with another author (MAP). Papers that meet the inclusion criteria will be ordered for a full review.

Following data extraction form will be applied:

	A	B
	Registration number of the Trial	Number
		CD primary endpoint
		CD secondary endpoint
		CD exploratory endpoint
		CCI primary endpoint
		CCI secondary endpoint
		CCI exploratory endpoint
	Invasive discipline	1= Abdominal Surgery
		2= Transplant
		3= Urology
		4= Orthopedics
		5= Gynecology
		6= Emergency
		7= Thoracic surgery
		8= Vascular surgery
		9= ICU
		10=Radiology
		11= Gastroenterology
		12= Angiology
		13= Other fields with invasive procedures (Free text to specify)
		year
		1= Europe

	A	B
	Year of publication	2= North America
		3= South America
		4= Asia
		5= Australia/New Zealand
		6= Africa
	Modification of the CD or CCI used? (multiple answers)	Modified CD (to specify in the freetext)
		Modified CCI (to specify in the freetext)
		No modification

A further search for RCTs using CD and/or CCI as endpoints will be conducted in the reference lists of the included studies.

- Statistical analysis:

We will use descriptive statistics for the three research questions. Categorical variables will be presented as frequencies (N) and percentages (percentage), counts as median with interquartile range or mean with standard deviation. Missing values will be reported were applicable.

4.3 International Survey

We have been challenged with many questions over the years mostly on how to rank some postoperative events. A comprehensive survey will be designed to identify such challenging points. These points are then discussed within a core group (at least FA, MP, AD, MAP, PAC) with the aim
to provide some guidance on how to use the CD classification and the CCI® to achieve consistency in the application of both classifications.

The questionnaire consists of three parts: 1) personal identification details, 2) general questions and FAQ on CD classification and CCI®, and 3) specific clinical scenarios.

- General Questions & FAQ:

A selection of questions raised in various benchmark studies, in the weekly morbidity and mortality (M&M) conferences of the University Hospital Zurich and by visitors to the assessurgery.com or cci-calculator.com website who contact us via the contact form.

- Clinical scenarios:

A selection of scenarios that have repeatedly led to discussions at M&M conferences on CD classification and the calculation of the CCI®. Furthermore, scenarios from the 5-year experience paper on CD classification and the 3-year experience paper on CCI® for which no consensus could be found among the survey participants.

We defined 7 groups of clinical scenarios:

1. Complications requiring repetitive interventions
2. Recurrent complications after intermittent healing
3. Invasive diagnostic interventions
4. Expected sequelae
5. Complications of increasing severity depending one from each other
6. Unrelated Complications/Death
7. Patient referral due to complications

Space will be provided for free text comments in relation to each question and scenario.

- Source population:

Panel of international academic surgeons invited based on a broad network of the authors.

- Software:

LimeSurvey

- Sample Size Calculation:

Not needed, as consequences are only adjustments.

- Analysis of the survey:

First a descriptive analysis will be performed. Then a core group consisting of the co-authors (FA, MP, AD, MAP, PAC) will meet and discuss all questions and scenarios of the survey. Based on the survey results and the discussion, the core group will finally make a classification recommendation for all questions and scenarios.
Survey participants who leave valuable comments on a question or scenario will be contacted personally, if necessary, and included in the discussion.

References

5

1. 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**(2): 205-13.

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