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Validation of the Clavien-Madadi Classification for Unexpected Events in Pediatric Surgery: A Collaborative ERNICA Project



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ABSTRACT

Background: The Clavien-Madadi classification is a novel instrument for the assessment and grading of unexpected events in pediatric surgery, based on the Clavien-Dindo classification. The system has been adjusted to better fit the pediatric population in a prospective single-center study. There is a need now to validate the Clavien-Madadi classification within an international expert network.

Methods: A pediatric surgical working group created 19 case scenarios with unexpected events in a multi-staged process. Those were circulated within the European Reference Network of Inherited and Congenital Anomalies (ERNICA) and surgeons were instructed to rate the scenarios according to the Clavien-Madadi vs. Clavien-Dindo classification.

Results: 59 surgeons from 12 European countries completed the questionnaire. Based on ratings of the case scenarios, the Clavien-Madadi classification showed significantly superior agreement rates of the respondents (85.9% vs 76.2%; $p < 0.05$) and was less frequently considered inaccurate for rating the pediatric population compared to Clavien-Dindo (2.1% vs 11.1%; $p = 0.05$). Fleiss' kappa analysis showed slightly higher strength of agreement using the Clavien-Madadi classification (0.74 vs 0.69). Additionally, intraclass correlation coefficient was slightly higher for the Clavien-Madadi compared to the Clavien-Dindo classification (ICC_{just} 0.93 vs 0.89; ICC_{unjust} 0.93 vs 0.89). More pediatric surgeons preferred the Clavien-Madadi classification for the case scenarios (43.0% vs 11.8%; $p = 0.002$) and advantages of the Clavien-Madadi were confirmed by 81.4% of the surgeons.

Conclusion: The Clavien-Madadi classification is an accurate and reliable instrument for the grading of unexpected events in pediatric surgery. We therefore recommend its application in clinical and academic pediatric surgical practice.

Level of Evidence: III.

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1. Introduction

Severity grading systems for postoperative complications have been used over decades for the assessment, documentation and

classification of serious adverse events in adult surgery [1,2]. Those systems have contributed to an increasing uniformity of negative outcome reporting and a better comparability of distinct time periods in a single center and of results between different centers [3]. The Clavien-Dindo classification, the most prominent severity grading system, has been validated in numerous prospective studies and has proven to be applicable and reproducible for that purpose [4–6]. Recently, the Clavien-Dindo classification has been recommended for the assessment of (general) surgical postoperative outcomes in a highly rated international consensus conference [7].

For the transfer of the reported advantages of severity grading systems into pediatric surgical practice, an increasing number of pediatric surgeons adopted the Clavien-Dindo classification into their clinical and academic routine within the last decade [8]. Since then, the classification has been inconsistently applied in pediatric surgery and has not been validated in children [8,9]. Meanwhile, several drawbacks of this instrument when applied to pediatric cohorts have been reported [10–12]. Therefore, a multidisciplinary expert group aimed to modify the classification to improve its accuracy in children [13].

This working group consisted of pediatric and general surgeons, statisticians, methodologists and was supported by the European Reference Network for rare Inherited and Congenital Anomalies (ERNICA) [13]. Within this process several modifications were made to the Clavien-Dindo classification: re-interventions are now graded according to their invasiveness rather than the anesthetic management, organ dysfunctions are reduced to a single grade and the implementation of organizational and management errors is another novelty to surgical severity grading systems.

In a recently published cohort of 17,502 children, the novel Clavien-Madadi classification detected significantly more events and showed a more accurate correlation with the complexity of procedures [13]. The methodology for the validation of the novel instrument was based on the protocol established by Dindo et al. for the Clavien-Dindo classification [14]. In this process, following the single-institution application and testing of the Clavien-Dindo classification, an international expert group was used to assess the acceptability and reproducibility of the classification [4].

In this study we set out to compare the Clavien-Dindo and Clavien-Madadi classification for unexpected events in pediatric surgery through an international survey within the ERNICA network, aiming to validate the novel instrument for future clinical and scientific practice.

2. Methods

Ethical approval for the validation of the Clavien-Madadi classification was obtained from the University Ethics Committee of Hannover Medical School (No. 10259_B0_K_2022) and the study was registered at clinicaltrials.gov prior to data analysis (NCT 05778019).

2.1. Definition of negative outcomes

One of the major amendments of the novel instrument is the revision of the definition of negative outcomes, abandoning the focus on “complications”, that mainly approach on postoperative (serious) adverse events, and concentrating now on “unexpected events”, which can occur any time from first preoperative presentation to the short- and long-term follow-up after surgery.

The definition of complications according to the Clavien-Dindo classification was mainly based on the Toronto-92 (T92) classification, including any deviations from the normal postoperative

course, that was later revised by the authors Clavien and Dindo to any deviations from the ideal postoperative course [3,15].

Unexpected events according to the Clavien-Madadi classification include any events with subsequent deviations from the planned pre-, intra- and postoperative courses of patients [13]. This broader definition allows to include several aspects, that are neglected by most of surgical severity grading systems: most importantly, organizational errors, management errors or postponement of surgery due to limited capacities (admission, surgery, anesthesia etc.) that result in a delayed treatment or recovery of patients.

2.2. Clavien-Dindo classification

The Clavien-Dindo classification is based on the interpretation and grading of the therapy used to treat a complication [14]. The seven grades used for the severity grading of those consequences of a complication refer to non-interventional and interventional strategies, the type of anesthesia used for (re-) interventions, organ impairments after complications and death (Table 1).

2.3. Clavien-Madadi classification

The modifications of the Clavien-Dindo classification resulting in the novel Clavien-Madadi classification have been previously published [13]. Briefly, the novel instrument is based on the consequences of an unexpected event, mostly referring to resolving or treating those events. The again seven grades include management and/or organizational errors, non-interventional and interventional strategies, (re-)interventions which are now stratified according to their invasiveness, organ impairments and death (Table 1).

2.4. Working group and methodology for case scenario construction and selection

For the establishment of the novel instrument, a multidisciplinary working group was established, including Pierre-Alain Clavien from the University Hospital of Zurich as the initial inventor of the Clavien-Dindo classification. For creation of the case scenarios, the working group was extended, including European pediatric surgeons from ERNICA affiliated centers (Germany, Sweden, Finland), and non-ERNICA affiliated centers (United Kingdom, Italy, Turkey).

The process for the selection of ideal case scenarios for an international survey consisted of the following steps:

1. All working group members contributed 20 case scenarios with unexpected events and complications in the management of children (preferably neonatal surgery);
2. Using the SurveyMonkey tool (SurveyMonkey, Palo Alto, California, United states), all case scenarios were circulated within the working group and were graded according to a Likert Scale (1 [not accurate] – 5 [most accurate]) regarding their plausibility and logic for an international survey;
3. The working group agreed on a final proposal of 19 case scenarios for the international survey.

2.5. International survey to assess acceptability and reproducibility of the classification

The final survey included 19 case scenarios and a questionnaire of 10 questions regarding the personal judgments about the classification (based on the Dindo et al. protocol [14]). The survey was circulated in March 2023 through the ERNICA network email

Table 1
The Clavien–Madadi classification for the grading of unexpected events in pediatric surgery and the Clavien–Dindo classification for the grading of postoperative complications in general surgery.

Grades	Clavien–Madadi classification	Grades	Clavien–Dindo classification
I	A Any deviation from the planned course due to management and/or organizational problems	I	Any deviation from the normal postoperative course with the need for pharmacological treatment Allowed therapeutic regimens are: drugs as antiemetics, antipyretics, analgetics, diuretics, electrolytes, and physiotherapy
B	Any deviation from the planned clinical course with the need for pharmacological treatment, such as antiemetics, antipyretics, analgetics, diuretics, electrolytes, and physiotherapy		This grade also includes wound infections opened at the bedside
II	Requiring pharmacological treatment with drugs other than such listed for Grade Ib	II	Requiring pharmacological treatment with drugs other than such allowed for Grade I complications Blood transfusions and total parenteral nutrition are also included
III	A Endoscopic and radiological-guided interventions Interventions via laparoscopy/thoracoscopy Interventions under anesthesia (other than such listed for Grade IIIb) Interventions via laparotomy/thoracotomy	III	A Intervention not under general anesthesia
B		B	Intervention under general anesthesia
IV	Multi-organ dysfunction^a	IV	A Single organ dysfunction (including dialysis)
V	Death of a patient	V	B Multiorgan dysfunction

^a Multi-organ dysfunction is defined as the concurrent dysfunction of two or more organs or systems including respiratory, cardiovascular, hematological, neurological, gastrointestinal, hepatic, and renal.

distribution list and was open for response during six weeks. Respondents were asked to specify their surgical discipline, level of experience (junior, senior, experienced), ERNICA affiliation and the country they practice in.

ERNICA is a network of healthcare professionals from specialized centers with 40 member hospitals in 12 European countries and 13 affiliated partners from 9 European countries. The goal of the network is to gather disease-specific expertise and resources, to implement high-quality care, reduce inequalities and make information accessible to healthcare providers, patients and their families across Europe.

The survey and questionnaires were filled out and analyzed anonymously using the SurveyMonkey (SurveyMonkey, Palo Alto, California, United states).

2.6. Statistical analyses

For the case scenario survey, agreement rates were defined as the matching grading of the unexpected events and complications (according to the Clavien–Madadi and Clavien–Dindo classification) by the surveyed surgeons and the initial grading by the working group. Thus, the working group grading of the case scenarios was determined “correct answers”. The agreement rates were obtained via the percentages of correct answers of surgeons compared to the interpretation of the working group.

Furthermore Fleiss' kappa, Kendall's coefficient of concordance as well as the intraclass correlation coefficient were analyzed for both the Clavien–Madadi and the Clavien–Dindo to assess interrater agreement and interrater reliability. Due to the ordinal nature of the analyzed variables Clavien–Madadi and Clavien–Dindo the Kendall coefficient of concordance (W) was used since it is suitable for assessing agreement between ordinal variables assessed by multiple raters. Kendall's W indicates the degree of association of ordinal assessments made by multiple raters when assessing the same scenarios. In addition, Fleiss' kappa and an intraclass correlation coefficient were calculated as sensitivity analyses despite these interrater indices being more suited for nominal/categorical data (Fleiss' Kappa) or interval and ratio data (ICC) assessed by multiple raters respectively. The null hypotheses for all three interrater indices was that the degree of agreement between raters is due to chance (e.g. the respective index is 0).

For Fleiss' kappa values between 0.61 and 0.80 were considered as a good agreement between raters, values exceeding 0.81 were considered as a very good agreement [16,17]. Values for Kendall's coefficient of concordance of 0.9 or higher were considered very good. The intraclass correlation coefficient was calculated using an ICC 3,1 (single measure) two-way-mixed model with people effect as random and measures effects as fixed assessing the absolute agreement (ICC_{unjust}) as well as consistency of ratings (ICC_{just}). ICC values of 0.75 or higher were considered as excellent reliability [18].

For all analyses, P < 0.05 was considered significant. Statistical analyses were made by a biostatistician of the Institute of Biostatistics at the Hannover Medical School using IBM SPSS Statistics 28.

3. Results

3.1. Demographic information of the surveyed surgeons

All member institutions and affiliated partners of the ERNICA network were contacted. Fifty-nine (62.1%) out of 95 respondents completed the survey. For the further analysis only completed surveys were analyzed. The responding pediatric surgeons were working in Germany (n = 12/20.3%), Sweden (n = 11/18.6%), Italy (n = 10/16.9%), Finland (n = 7/11.9%), Spain (n = 5/8.5%), the Netherlands (n = 3/5.1%), the United Kingdom (n = 3/5.1%) Czech

Republic (n = 3/5.1%), Turkey (n = 2/3.4%) [non-ERNICA centers], Croatia (n = 1/1.7%), Denmark (n = 1/1.7%) and France (n = 1/1.7%).

Out of the surveyed surgeons, five (8.5%) were junior level, 13 (22.0%) senior resident level surgeons and 41 (69.5%) were experienced surgeons, with at least 10 years of practice.

3.2. Agreement rate of surgeons rating the 19 case scenarios according to the Clavien-Madadi classification

The agreement rate (Table 2) was >90% in 11 cases (57.9%), 70–90% in 5 cases (26.3%) and 50–70% in 3 cases (15.8%). No agreement rate less than 52.5% was recorded for the case scenarios. Stratifying the agreement results to each Grade of the Clavien-Madadi classification, the agreement for Grade Ia cases was 86.5%, Grade Ib was 92.4%, Grade II was 72.9%, Grade IIIa was 88.1%, Grade IIIb was 93.8%, Grade IV was 75.1% and Grade V was 100%. The three cases (15.8%) with agreement rates less than 70% were Grade II, Grade Ia and Grade IV scenarios.

For 9 presented cases (47.4%), a minority of surveyed surgeons responded that the Clavien-Madadi classification is not applicable (non-applicability rating) for the grading of the case scenarios. In detail, 5 of those 9 scenarios (55.6%) had a non-applicability rating less than 2%, 3 scenarios (33.3%) less than 7% and in one scenario the non-applicability was attested by 17% of surgeons. Interestingly, the scenario with the highest non-applicability rating of the Clavien-Madadi classification, was determined Grade II by the majority of surgeons (Grade II of the Clavien-Madadi classification has no modifications on the Clavien-Dindo classification).

3.3. Comparison of grading according to the Clavien-Madadi versus Clavien-Dindo classification

The agreement rate of the Clavien-Dindo classification for the 19 cases scenarios was significantly inferior to the Clavien-Madadi classification (76.2% vs 85.9%; p < 0.05) (Table 3).

Non-applicability of the Clavien-Madadi classification was attested significantly less frequent than for the Clavien-Dindo classification (2.1% vs 11.1%; p 0.05).

Significantly more surgeons preferred the Clavien-Madadi classification for the 19 pediatric case scenarios (43.0% vs 11.8%; p = 0.002). Advantages of the Clavien-Madadi classification over the Clavien-Dindo classification were confirmed by 81.4% and 93.0%

of the surgeons would consider the Clavien-Madadi classification for future research.

Analysis of Fleiss' kappa showed significant substantial agreement for both Clavien-Madadi (0.74; 0.74–0.75; p < 0.001) and Clavien-Dindo (0.69; 0.68–0.69; p < 0.001), with the Clavien-Madadi having a slightly higher strength of agreement according to Fleiss' kappa.

The values for Kendall's coefficient of concordance revealed that raters applied the same standard when assessing case scenarios via Clavien-Madadi (W = 0.91; p < 0.001) and Clavien-Dindo (W = 0.91; p < 0.001), with both showing a very good association.

In addition to Fleiss' kappa and Kendall's W the intraclass correlation coefficient was calculated and analyzed using an ICC 3,1 (single measure) two-way-mixed model (with people effect as random effects and measures effects as fixed effects). For the Clavien-Dindo the results for the ICC showed significant and excellent reliability in both absolute agreement (ICC_{unjust} = 0.89; 0.81–0.95; p < 0.001) and consistency of ratings (ICC_{just} = 0.89; 0.81–0.95; p < 0.001). ICC results for Clavien-Madadi also showed significant and excellent reliability with slightly higher values for absolute agreement (ICC_{unjust} = 0.93; 0.88–0.97; p < 0.001) and consistency of ratings (ICC_{just} = 0.93; 0.88–0.97; p < 0.001).

3.4. Advantages and disadvantages of the Clavien-Madadi classification

Advantages and disadvantages of the Clavien-Madadi classification were reported through free-text feedbacks in a non-uniform matter. Benefits of the introduction of organizational and management alterations were reported by 45.8% of surgeons (versus 5.1% disagreeing with the Grade Ia), while 33.9% preferred the novel stratification of the Grade III according to the invasiveness rather than the anesthesiologic management of procedures (versus 6.8% preferring the differentiation of anesthesia). Two surgeons (3.4%) welcomed the reduction of the organ-failures to a single group of multi-organ dysfunctions. In contrast, 15.3% of respondents were missing the differentiation of single- and multi-organ failure, with the majority referring to kidney failures, especially in the group of older children and adolescents.

One surgeon (1.7%) reported to miss the inclusion of misdiagnosis in the classification system as a novel aspect.

Table 2
Agreement rate (%) for each clinical scenario according to the Clavien-Madadi classification.

Grading according to the Clavien-Madadi classification									
Case no.	Ia	Ib	II	IIIa	IIIb	IV	V	Not applicable	Rating by Working group
1	1.7%	13.6%	84.8%						II
2			1.7%	93.2%	5.1%				IIIa
3				6.8%	91.5%	1.7%			IIIb
4	94.9%							5.1%	Ia
5		1.7%			1.7%	89.8%		6.8%	IV
6				72.9%	27.1%				IIIa
7	1.7%	17.0%	79.7%					1.7%	II
8	96.6%	1.7%						1.7%	Ia
9							100%		V
10				98.3%	1.7%				IIIa
11		93.2%	3.4%	1.7%				1.7%	Ib
12			1.7%		15.3%	83.1%			IV
13	3.4%	20.3%	54.2%	5.1%				17.0%	II
14	67.8%	1.7%	23.7%					6.8%	Ia
15							100%		V
16				5.1%	94.9%				IIIb
17	3.4%	91.5%	1.7%	1.7%				1.7%	Ib
18			3.4%	37.3%	5.1%	52.5%		1.7%	IV
19				3.4%	94.9%	1.7%			IIIb

Table 3
Agreement rate (%) for each clinical scenario according to the Clavien-Dindo classification.

Grading according to the Clavien-Dindo classification									
Case no.	I	II	IIIa	IIIb	IVa	IVb	V	Not applicable	Rating by Working group
1	16.8%	78.8%		1.7%	1.7%				II
2		1.7%	6.3%	90.3%	1.7%				IIIb
3				76.6%	23.4%				IIIb
4	32.8%							67.2%	n.a.*
5	1.7%				1.7%	90.1%		6.5%	IVb
6			1.7%	94.9%	1.7%	1.7%			IIIb
7	18.0%	80.3%						1.7%	II
8	27.1%	1.7%						71.2%	n.a.*
9				1.7%			98.3%		V
10			3.3%	96.7%					IIIb
11	91.5%	3.4%	5.1%					1.7%	I
12				13.6%	10.2%	76.2%			IVb
13	18.6%	55.9%	8.5%	3.4%				13.6%	II
14	17.0%	28.8%						54.2%	n.a.*
15							100%		V
16					100%				IIIb
17	89.8%	3.4%	5.1%	1.7%					I
18		1.7%	17.0%	23.7%	8.4%	49.2%			IVb
19				93.2%	5.1%	1.7%			IIIb

n.a.* = not applicable.

3.5. Logic and feasibility of the Clavien-Madadi classification

It took the majority of surveyed surgeons (71.2%) less than 10 min to understand the principle of the Clavien-Madadi classification. The principle remained unclear for one individual. The Clavien-Madadi classification was considered simple by 93.2%, reproducible by 98.3%, logical by 96.6% and useful in 94.9%. The vast majority (94.9%) think that the Clavien-Madadi classification respects patients and hospitals perspectives.

4. Discussion

After decades of inadequate surgical outcome reporting, in 1992 Clavien et al. advocated for the introduction of severity grading systems [3]. The aims of such systems were the standardization of reporting, increasing comparability between time periods, centers, surgery and non-surgical treatment and improving data sets for adequate metaanalysis. Since the introduction of the Clavien-Dindo classification in 2004 severity grading systems have become an integral part of clinical studies in general surgery [14].

The increasing application of the Clavien-Dindo classification in the pediatric surgical literature is an indicator for the demand of uniform reporting of outcomes [8]. Instead of transferring instruments from general surgery into pediatric surgical practice, our multidisciplinary international study group was aiming for a validated severity grading system in pediatric cohorts with the novel Clavien-Madadi classification [13].

The two-stage validation process started with the testing of the instrument in a prospective study, proving the feasibility and applicability for the grading of unexpected events in a tertiary pediatric surgical institution. In the previously published analysis we showed a significant higher number of events detected by the novel instrument and superior correlation of procedure complexity and event grading with the Clavien-Madadi compared to the Clavien-Dindo classification (ρ 0.76 vs ρ 0.25) [13].

In the second step, adapting the protocols by Dindo et al. [4,14], Mitropoulos et al. [19] and Dell-Kluster et al. [20], we now aimed to obtain feedback from members of the ERNICA pediatric surgical network using case scenarios of unexpected events and complications.

The 19 case scenarios, designed by the study group in numerous stages, included adverse events and their management in neonates, children and adolescent covering the broad spectrum of neonatal and pediatric surgery. The surveyed surgeons were instructed to grade the severity of the events according to the Clavien-Madadi and Clavien-Dindo classification and were furthermore asked to specify their preferred instrument.

The obtained responses concluded a superior agreement of surgeons (of correct answers) grading the case scenarios using the Clavien-Madadi classification (85.6 vs 72.9%). In addition, 58% of the surveyed surgeons preferred the Clavien-Madadi over the Clavien-Dindo classification and advantages of the Clavien-Madadi classification were reported by 82% of the surveyed surgeons.

However, considering the agreement of multiple raters assessing multiple items in our survey, results showed per definition very good agreement for both the Clavien-Dindo classification and the Clavien-Madadi classification considering the Kendall's coefficient of concordance, Fleiss' Kappa and the intraclass correlation coefficient [ICC 3,1 (single measure) two-way-mixed model]). Results for these interrater indices were nearly identical for both severity grading systems, with slightly better results for the Clavien-Madadi for Fleiss' Kappa and the ICC, which could have resulted from one rater not rating two scenarios for the Clavien-Dindo classification.

The results of the case scenarios and the survey for the Clavien-Madadi classification in pediatric surgery are equivalent to the numbers by Dindo et al. [14] for the validation of the Clavien-Dindo classification in general surgery and are superior to the results by Mitropoulos et al. for the Clavien-Dindo classification in urology [19]. Despite the lower agreement numbers for the Clavien-Dindo classification using urological case scenarios (compared to the Clavien-Madadi validation) in the studies by Mitropoulos et al. [19] and Poletajew et al. [21], the European Association of Urology (EAU) Guideline Panel recommended the Clavien-Dindo classification for urological practice. However, Mitropoulos et al. emphasized the necessity of modifications for a better applicability in urological cohorts [19]. In contrast to the EAU statement, Dwyer et al. reported the inaccuracy of the Clavien-Dindo classification in pediatric urology [22]. In an international survey the authors showed significantly lower agreement numbers of pediatric compared to the adult urological case scenario gradings according to the Clavien-Dindo classification [22].

Whilst modifications of the Clavien-Dindo classification have been tested for (pediatric) orthopedic surgery [23,24], head and neck surgery [25,26] and spine [27,28] surgery, the studies mostly relied on either application of the instruments in single institutions or surveys with case scenarios. However, the protocols conducted by Dindo et al. [14] for the Clavien-Dindo classification and Dell-Kuster et al. [20] for the ClassIntra classification of intraoperative events offer a rigorous methodology for the validation, consequently resulting in the numerous application of the instrument in practice. In fact, the multidisciplinary setting of our working group for the Clavien-Madadi classification is unique, including the supervision by adult surgeons that have already established the most prominent severity grading system in surgery.

The approval of 93% surveyed surgeons in the ERNICA network for the application of the Clavien-Madadi classification for future research is promising and may result in further standardization of outcome reporting within the academic network specialized on rare diseases. Based on those numbers, the ERNICA network recently decided to implement the Clavien-Madadi classification into the EPSA/ERNICA registry for inherited and congenital (digestive and intestinal) anomalies. In addition to numbers on the incidence of unexpected events in neonatal surgery, the results could provide information on the surgical morbidity of neonates with congenital anomalies. The Comprehensive Complication Index (CCI[®]) is a recently introduced metric for the assessment of surgical morbidity in (adult) general surgery and has been reported to be more sensitive than existing morbidity endpoints [29,30]. Whilst the CCI[®] is based on the Clavien-Dindo classification, a pediatric model using the Clavien-Madadi classification could be the topic of future research, as it has been recommended for the assessment of (general) surgical postoperative outcomes in a landmark international consensus conference.

Despite the promising results of the validation of the Clavien-Madadi classification limitations of our methodology should be acknowledged. Although ERNICA is a well-established expert network with high quality standards, the representation of the global pediatric surgical community can only be speculated. Additionally, a bias of the working group designing the case scenarios was certainly present, taking into account that some of the working group members were part of the core team conceptualizing the Clavien-Madadi classification. We tried to reduce this bias with the consensus (multi-stage) selection of the case scenarios by the working group, excluding the principal investigators (O.M.S., B.M.U., J.F.K., J.B.) of the study from the selection process. Finally, the case scenarios for the validation of the Clavien-Madadi classification are more detailed and complex compared to the general surgical and urological studies. It can be argued that the additional information helped with the grading of the scenarios, but for some case scenarios it might have led to the identification of multiple unexpected events and therefore misinterpretation and heterogeneous grading. However, our survey covered a broader spectrum of diseases from neonatal surgery to procedures in adolescent which made most of the detailed scenarios necessary.

Despite those drawbacks, the results of the ERNICA collaborative project for the validation of the Clavien-Madadi classification for the documentation of unexpected events in pediatric surgery confirm the accuracy of the instrument in pediatric surgical cohorts.

We therefore strongly recommend its application in the clinical and academic routine of pediatric surgeons.

Sources of funding

This work was financed by the general budgets of the departments involved.

Conflicts of interest

None of the authors have any conflicts of interest to declare.

Appendix

Case Scenario #1

A 3-year-old girl underwent removal of a left submandibular lymph node for suspected atypical mycobacteriosis. In the postoperative period a slight mouth deviation was noticed. Following oral steroid therapy with betamethasone for 7 days, significant reduction of the facial asymmetry was documented at follow-up, with complete resolution 30 days after surgery.

Case Scenario #2

Laparoscopic appendectomy was performed in a 12-year-old boy 2 weeks after onset of symptoms. On postoperative day 5, he experienced pain in the lower back. Ultrasound revealed a loculated abscess in the pelvis which necessitated percutaneous drainage via interventional radiology under general anesthesia. The patient was discharged on postoperative day 10.

Case Scenario #3

A 12-year old patient with acalculous cholecystitis underwent difficult laparoscopic cholecystectomy. Postoperatively patient became jaundiced with increased liver function tests. Imaging was highly suspicious for common hepatic duct injury. Re-laparoscopy revealed clipping and cutting of the common hepatic duct. Laparotomy was performed with hepatico-jejunostomy.

Case Scenario #4

An 8-month-old boy underwent first-stage Fowler-Stephens procedure for intra-abdominal testis. The second stage was scheduled 6 months after the first. Due to the lockdown caused by the SARS-CoV-2 pandemic and the subsequent waiting list, the operation was instead performed 5 months later, therefore 11 months after the first stage, without intra- nor post-operative surgical complications.

Case Scenario #5

A newborn girl (25 weeks of gestation, birth weight 860 g) experienced abdominal distension on 67th day of life with leucopenia and thrombocytopenia. Abdominal x-ray showed possible volvulus. After laparotomy midgut volvulus was confirmed, she underwent small bowel resection and a second look laparotomy 2 days later. At the second laparotomy necrotic bowel was removed and she was left with 20 cm of small bowel and rectum. Due to septic shock, she had kidney failure and brain hemorrhage. She recovered, but is left with chronic kidney dysfunction, intestinal failure due to short bowel syndrome and cerebral palsy (CP).

Case Scenario #6

A 7-month-old boy with prenatal diagnosis of a right lower lobe congenital pulmonary malformation underwent elective thoracoscopic lobectomy. Eight hours after the end of the procedure, increased drainage of blood from the chest drain was detected, with slight tachycardia. A chest x-ray showed a fluid layer occupying the right costophrenic sinus. The child was taken to the operating room for a re-thoracoscopy, during which an intermittent bleeding was

detected from a small hilar arterial vessel, which was ligated using clips and ties. The patient was discharged 6 days later, without further complications.

Case Scenario #7

An 11-year-old girl with thyrotoxicosis underwent elective thyroidectomy. After the operation she had an allergic reaction (itching, eczema of the body and limbs, nausea) due to unknown reason. After steroids (prednisolone) and anti-histamine treatment, the symptoms resolved.

Case Scenario #8

A 1-day old boy with type C esophageal atresia arrived to the operating room from NICU for bronchoscopy and esophageal atresia repair. Blood products were not booked to be ready if needed and therefore the OR team had to wait for extra 2 h before the operation could start.

Case Scenario #9

A patient affected by long-gap esophageal atresia underwent esophageal replacement by colonic transposition at the age of 8 months. On the fourth postoperative day, due to fever and increase of inflammatory markers, upper endoscopy was performed, which showed extensive necrosis of the transposed colon. The patient was urgently taken to the operating room for the removal of the colonic segment and the creation of a cervicostomy and gastrostomy. However, due to the severe mediastinitis that has developed and the consequent sepsis, the patient died six days after the second operation.

Case Scenario #10

A 17-year-old girl with solid pseudopapillary tumor of the pancreatic tail (Frantz tumor) underwent open left sided pancreatectomy, splenectomy. The pancreatic parenchyma was divided using a stapler. Postoperatively, the patient developed a pancreatic fistula to a cavity in the left upper quadrant and underwent imaging via MRI. To drain the pancreas the pancreatic duct was stented via ERCP under general anesthesia. Subsequently the pancreatic fistula resolved with full recovery.

Case Scenario #11

A newborn with esophageal atresia underwent an open repair with direct anastomosis of the segments at day two of life. On postoperative day 4 the infant was doing well, no fever or signs of systemic infection but the wound was swollen, red and painful on palpation. A bedside drainage of the wound infection was performed.

Case Scenario #12

A 3-day-old boy underwent open primary repair for left-sided congenital diaphragmatic hernia. On postoperative day 8 inflammatory markers and lactate increased. Chest xray was highly suspicious for recurrence. Re-laparotomy confirmed recurrence, with strangulated short bowel and massive ischemia. Small bowel was resected with primary anastomosis. Postoperatively the patient developed sepsis, with anuria, increased retention parameters and elevated liver function tests. Patient remained intubated for several days.

Case Scenario #13

A 3-month-old boy with an anorectal malformation without fistula suffered urethral injury during posterior sagittal anorectoplasty (posterior wall of urethra accidentally opened). In this case, the Foley catheter was left in place for 1 week (usually only 3 days) with prophylactic antibiotics to prevent urinary tract infection.

Case Scenario #14

A 1-year old boy with Wilms tumor and vena cava thrombus extending to the right atrium was planned for surgery with ECMO as a back-up. Surgery was postponed several times due to low intensive care unit capacities, therefore, the patient had to undergo an additional cycle of chemotherapy.

Case Scenario #15

A 2-year old girl with a history of duodenal atresia, esophageal atresia and developmental delay, was diagnosed with stricture of the esophago-gastric anastomosis and bilateral vocal cord paralysis following complicated esophageal atresia reconstruction with gastric pull up. Despite multiple dilatations, the stricture did not resolve. She developed a respiratory failure due to mucus secretions and vocal cord paralysis and was intubated. The stricture was resected through the neck incision and new end-to-end anastomosis was made. In the same operation she had a tracheostomy formed. On fourth postoperative day she was septic and had massive bleeding from the neck wound. She was diagnosed with anastomotic leak, jugular vein aneurysm and tracheal wall defect due to extensive infection. She died due to complications of the surgery and septic shock.

Case Scenario #16

A 22-day-old newborn underwent laparoscopic pyloromyotomy for hypertrophic pyloric stenosis. Abdominal distension and vomiting persisted 14 h after surgery and abdominal x-ray showed a significant amount of free air in the peritoneum. 16 h after the first operation, the child was taken back to the operating room for laparotomy and closure of the duodenal perforation. The child was discharged on the 7th postoperative day without further complications.

Case Scenario #17

2.5-month-old boy with type C esophageal atresia (repaired on first day of life), anorectal malformation with rectoperineal fistula underwent an elective anoplasty and stoma closure. The in house postoperative recovery was uneventful. He was discharged on the third postoperative day. On the 5th postoperative days the patient returned to the hospital due to wound infection (stoma closure wound). The wound was opened bed side and cleaned. Patient was discharged the same day with wound care instructions. Wound healed without any further problems.

Case Scenario #18

A 3-month-old girl with type A esophageal atresia and Downs syndrome underwent delayed thoracoscopic anastomosis. Postoperatively the patient suffered a complicated course with anastomotic leakage with mediastinitis, reintubation, sepsis, severe SIRS, hypotension and application of vasoactive pressors. The management of the patient included drainage via chest tube,

intravenous broad-spectrum antibiotics and ICU management. The patient finally recovered and the anastomosis healed without further intervention.

Case Scenario #19

In the hours following the placement of a CVC in the right subclavian vein, a 6-year-old patient became hemodynamically unstable and presented a massive right hemothorax. An emergency right thoracotomy was performed, which showed a laceration of the ipsilateral subclavian vein and which was repaired. The subsequent course was devoid of further complications.

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