Extended Clavien-Dindo classification of surgical complications: Japan Clinical Oncology Group postoperative complications criteria

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Abstract

Purpose Prior to publication of the Clavien-Dindo classification in 2004, there were no grading definitions for surgical complications in either clinical practice or surgical trials. This report establishes supplementary criteria for this classification to standardize the evaluation of postoperative complications in clinical trials.

Methods The Japan Clinical Oncology Group (JCOG) commissioned a committee. Members from nine surgical study groups (gastric, esophageal, colorectal, lung, breast, gynecologic, urologic, bone and soft tissue, and brain) specified postoperative complications experienced commonly in their fields and defined more detailed grading criteria for each complication in accordance with the general grading rules of the Clavien-Dindo classification.

Results We listed 72 surgical complications experienced commonly in surgical trials, focusing on 17 gastrointestinal complications, 13 infectious complications, six thoracic complications, and several other complications. The grading criteria were defined simply and were optimized for surgical complications.

Conclusions The JCOG postoperative complications criteria (JCOG PC criteria) aim to standardize the terms used to define adverse events (AEs) and provide detailed grading guidelines based on the Clavien-Dindo classification. We believe that the JCOG PC criteria will allow for more precise comparisons of the frequency of postoperative complications among trials across many different surgical fields.

Keywords JCOG postoperative complications criteria (JCOG PC criteria) · Clavien-Dindo classification · Postoperative complications

Introduction

The evaluation of postoperative complications in surgical trials is as important as the assessment of toxicities in chemotherapy trials. Prior to the proposal of a therapy-oriented classification scheme, by Clavien PA et al. in 1992 [1], there were no accepted definitions for the grading of surgical complications in clinical practice. This framework proposed by Clavien et al. was not used widely, because there was no system for the grading of severity of surgical complications [2] and no uniform definition of these events. For instance, some surgeons included a body temperature greater than 38 °C on two consecutive days as being...
“high”, whereas others included intraoperative complications, postoperative complications (within 30 days), and late events such as dumping syndrome. Few randomized controlled trials (RCTs) [3] have used this classification system, with individual parochial definitions of surgical complications being used in most surgical RCTs [4–6].

In cancer clinical trials, adverse events (AEs) are evaluated in accordance with the Common Terminology Criteria for Adverse Events (CTCAE), which is far from exhaustive in terms of surgical complications; thus, some surgeons are not comfortable using grading definitions. The Clavien-Dindo classification, published in 2004 [4] defined a simple classification of postoperative complications, which has been adopted widely in clinical practice. Although this classification categorizes postoperative complications broadly into four major groups, it is often desirable to more clearly define the common AEs to avoid the use of different or less precise terms for the same AEs occurring in different clinical trials. More detailed grading criteria for common AEs would also be helpful for surgeons. Therefore, our aim was to establish supplementary criteria for the Clavien-Dindo classification to standardize the evaluation of postoperative complications.

Methods

The Japan Clinical Oncology Group (JCOG) commissioned a committee to establish more precise criteria for the grading of surgical complications. The committee comprised members from nine JCOG study groups (gastric, esophageal, colorectal, lung, breast, gynecologic, urologic, bone and soft tissue, and brain) who have extensive experience with surgical trials. These groups established the JCOG postoperative complications criteria (JCOG PC criteria). Members identified the postoperative complications experienced commonly in their fields and defined detailed grades for each complication in accordance with the general grading rules of the Clavien-Dindo classification. The JCOG PC criteria were reviewed and approved by the JCOG Executive Committee and published on the JCOG website in October, 2011 (in Japanese) [8].

Results

The JCOG PC criteria included 72 surgical AEs experienced commonly in surgical trials, including 17 gastrointestinal complications, 13 infectious complications, six thoracic complications, and several other complications (Table 1). If no applicable AE terms are found in the JCOG PC criteria, ‘other (specify)’ should be chosen. In such cases, the appropriate AE term should be used, and the overall grading should be performed in accordance with the general rules of the Clavien-Dindo classification. Because the grading definitions follow the general rules of the Clavien-Dindo classification, surgeons can use these original rules to grade AEs, and can also refer to the more detailed definitions in the JCOG PC criteria if necessary. Table 2 lists the differences between CTCAE, the Clavien-Dindo classification, and the JCOG PC criteria.

Discussion

Until Clavien PA et al. published their original classification in 1992, there were no established criteria or framework available to standardize surgical complications in surgical trials. In 2003, the US National Cancer Institute-Common Toxicity Criteria (NCI-CTC) version 2.0 [9] were revised and renamed the CTCAE version 3.0 [10]. This system has been used widely to evaluate and define the toxicity of chemotherapy or radiotherapy. While terms and definitions for AEs occurring as a result of intraoperative and postoperative complications were not included in the NCI-CTC version 2.0, some surgical AE terms were incorporated in the CTCAE version 3.0. Nevertheless, the CTCAE version 3.0 failed to include many surgical complications and surgeons were frequently unable to objectively classify complications using its grading definitions.

In 2009, the CTCAE version 4.0 [11] was released, with considerably more surgical AE terms, but several common surgical complications were still not included. For example, intra-abdominal abscess, pyothorax, delayed gastric emptying, and lung torsion were not listed as AE terms. Moreover, grading definitions were not clinically optimized for some surgical AEs. For example, the grading definition of pancreatic fistula in this version of the CTCAE is suitable for pancreatitis, but not for pancreatic fistula after pancreatectomy. Such inappropriate definitions have made surgeons reluctant to use the CTCAE version 4.0 in surgical trials.

In 2004, the Clavien-Dindo classification was modified to allow for the grading of life-threatening complications and long-term disability caused by a complication. This revised version defines five grades of severity (Grade I, II, IIIa, IIIb, IVa, IVb, and V) and the suffix “d” (for “disability”) is used to denote any postoperative impairment [7]. This refined Clavien-Dindo classification has been used increasingly in clinical practice and also in clinical trials involving surgical procedures, because it is simple, reproducible, and flexible [12]. Rather than providing specific grading criteria for each AE, the Clavien-Dindo classification provides broad-based but general criteria that can be used uniformly for all kinds of surgical AEs. However, several issues have emerged since this classification became
### Table 1 List of surgical adverse event (AE) terms and gradings

| Principle of grading | I | II | IIIa | IIIb | IVa | IVb | V | Supplemental explanation of suffix “d” |
|----------------------|---|---|------|------|-----|-----|---|---------------------------------------|

#### AE term

- **Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic, or radiological interventions. Allowed therapeutic regimens include drugs such as antiemetics, antipyretics, analgesics, diuretics, electrolytes, and physiotherapy. This grade also includes wound infections opened at the bedside.**

- **Requirement for pharmacological treatment with drugs other than those allowed for grade I complications. Blood transfusions and total parenteral nutrition are also included.**

- **Requirement for surgical, endoscopic or radiological intervention not under general anesthesia.**

- **Life-threatening complications (including CNS complications) requiring IC/ICU management. Single organ dysfunction (including dialysis).**

- **Life-threatening complications (including CNS complications) requiring IC/ICU management. Multiple organ dysfunction.**

- **Death of the patient.**

- **If the patient suffers from a complication at the time of discharge, the suffix “d” (for “disability”) is added to the respective grade of complication. This label indicates the need for a follow-up to fully evaluate the complication.**

#### Stroke

- **Clinical observation only; intervention not indicated.**

- **Medical management indicated (e.g., anticoagulant therapy).**

- **Radiological intervention without general anesthesia (e.g., intracerebrovascular treatment).**

- **Intervention under general anesthesia indicated (e.g., drainage, surgical clipping, cerebrovascular bypass, carotid endarterectomy).**

- **IC/ICU management indicated.**

- **IC/ICU management indicated; associated with respiratory failure.**

- **Death.**

- **Persistent hemiplegia.**

#### Recurrent laryngeal nerve palsy

- **Clinical observation or diagnostic evaluation only; intervention not indicated.**

- **Aspiration; medical management indicated (e.g., antibiotics).**

- **Severe aspiration; food intake almost impossible; medical intervention under local anesthesia indicated (e.g., vocal cord injection, tracheal puncture).**

- **Intervention under general anesthesia indicated (including tracheostomy under sedation).**

- **Mechanical ventilation indicated.**

- **Sepsis or multiple organ failure.**

- **Death.**

- **Hoarseness, difficulty in speaking; communication through writing necessary; discharged with tracheostomy.**

#### Upper extremity paresthesia

- **Clinical observation only; intervention not indicated.**

- **Medical management indicated.**

- **Surgical intervention without general anesthesia indicated (e.g., nerve block).**

- **Surgical intervention without general anesthesia indicated (e.g., nerve block).**

- **Surgical intervention without general anesthesia indicated (e.g., nerve block).**

- **Persistent brachial paresthesia.**

#### Paresthesia in resected part (Phantom pain)

- **Clinical observation only; intervention not indicated.**

- **Medical management indicated.**

- **Surgical intervention without general anesthesia indicated (e.g., nerve block).**

- **Surgical intervention without general anesthesia indicated (e.g., nerve block).**

- **Surgical intervention without general anesthesia indicated (e.g., nerve block).**

- **Persistent phantom pain.**
| Principle of grading | I | II | IIIa | IIIb | IVa | IVb | V | Supplemental explanation of suffix “d” |
|---------------------|---|----|------|------|-----|-----|---|--------------------------------------|
| Ischemic heart disease | Clinical observation or diagnostic evaluation only; intervention not indicated | Medical management indicated (e.g., anticoagulant therapy) | Cardiac catheterization indicated | Intervention under general anesthesia indicated (coronary artery bypass) | Heart failure associated with low cardiac output syndrome; IC/ICU management indicated | Heart failure associated with low cardiac output syndrome and renal failure; IC/ICU management indicated | Death | Persistent heart failure following myocardial infarction |
| Pericardial effusion | Clinical observation or diagnostic evaluation only; intervention not indicated (drainage only through existing drainage tube) | Medical management indicated | Image-guided drain placement/paracentesis including drain replacement indicated | Intervention under general anesthesia indicated (fenestration) | Cardiac tamponade; IC/ICU management indicated | Cardiac tamponade and renal failure; IC/ICU management indicated | Death | – |
| Bradyarrhythmia | Clinical observation or diagnostic evaluation only; intervention not indicated | Medical management indicated (e.g., atropine, β agonists) | Medical intervention under local anesthesia indicated (e.g., pacemaker implantation) | – | Heart failure associated with low cardiac output syndrome; IC/ICU management indicated | Heart failure associated with low cardiac output syndrome and renal failure; IC/ICU management indicated | Death | – |
| Supraventricular arrhythmia | Clinical observation or diagnostic evaluation only; intervention not indicated | Medical management indicated (e.g., antiarrhythmic drugs) | Medical intervention under local anesthesia indicated (e.g., catheter ablation, synchronized cardioversion) | – | Heart failure associated with low cardiac output syndrome; IC/ICU management indicated | Heart failure associated with low cardiac output syndrome and renal failure; IC/ICU management indicated | Death | – |
| Ventricular arrhythmia | Clinical observation or diagnostic evaluation only; intervention not indicated | Medical management indicated (e.g., antiarrhythmic drugs) | Medical intervention under local anesthesia indicated (e.g., catheter ablation, external defibrillator, pacemaker implantation) | – | Heart failure associated with low cardiac output syndrome; IC/ICU management indicated | Heart failure associated with low cardiac output syndrome and renal failure; IC/ICU management indicated | Death | – |
| Atelectasis/sputum excretion difficulty | Clinical observation or diagnostic evaluation only; intervention not indicated, except for nebulizers, expectorants, or lung physiotherapy (e.g., postural drainage) | Medical management indicated (e.g., antibiotics) | Bronchoscopic aspiration or surgical intervention indicated (e.g., tracheal puncture) without general anesthesia | Intervention under general anesthesia indicated (including tracheostomy under sedation) | Mechanical ventilation indicated | Sepsis or multiple organ failure | Death | Discharged with tracheostomy |
Table 1 continued

| Principle of grading | I                | II               | IIIa             | IIIb             | IVa             | IVb             | V                | Supplemental explanation of suffix “d” |
|---------------------|------------------|------------------|------------------|------------------|-----------------|-----------------|------------------|----------------------------------------|
| Tracheal fistula, bronchial fistula | Clinical observation or diagnostic evaluation only; intervention not indicated | Procedure under local anesthesia indicated | Intervention under general anesthesia indicated | Mechanical ventilation indicated | Sepsis or multiple organ failure | Death | Discharged with tube drainage, open drainage |
| Pulmonary fistula | Clinical observation or diagnostic evaluation only; intervention not indicated (drainage only through existing drainage tube) | Procedure under local anesthesia indicated (e.g., chest tube drainage, pleurodesis) including drain replacement indicated. | Intervention under general anesthesia indicated (Closure for pleuroparenchymal defects, pleurodesis) | Mechanical ventilation indicated | Sepsis or multiple organ failure | Death | Discharged with tube drainage, open drainage |
| Chylothorax | Observation of chylous drainage fluid or thoracentesis fluid only (drainage only through existing drainage tube) | Fat-restricted diet, intravenous nutrition indicated | Image-guided drain placement/paracentesis including drain replacement indicated. | Intervention under general anesthesia indicated (e.g., thoracic duct ligation) | – | – | Death | Persistent respiratory distress, malnutrition |
| Pleural effusion | Clinical observation or diagnostic evaluation only; intervention not indicated (drainage only through existing drainage tube) | Medical management indicated (e.g., diuretics) | Image-guided drain placement/thoracentesis including drain replacement indicated | Intervention under general anesthesia indicated | Mechanical ventilation indicated | Multiple organ failure | Death | Persistent respiratory distress |
| Lung torsion | – | – | – | Intervention under general anesthesia indicated (e.g., detorsion, lobectomy) | Mechanical ventilation indicated | Sepsis or multiple organ failure | Death | – |
| Ascites | Clinical observation or diagnostic evaluation only; intervention not indicated (drainage only through existing drainage tube) | Medical management indicated (e.g., diuretics) | Image-guided drain placement/paracentesis including drain replacement indicated | Intervention under general anesthesia indicated | – | – | Death | Persistent abdominal fullness |
| Principle of grading | I | II | IIIa | IIIb | IVa | IVb | V | Supplemental explanation of suffix “d” |
|----------------------|---|----|------|------|-----|-----|---|---------------------------------------|
| Diarrhea             | Intestinal fluid excretion ≥ 2000 ml/day; intervention not indicated | Intestinal fluid excretion ≥ 2000 ml/day associated with dehydration or electrolyte abnormality; intravenous fluids indicated | – | – | At least one organ failure (e.g., pulmonary disorders requiring mechanical ventilation or nephropathy indicating dialysis) | Sepsis or multiple organ failure | Death | Significant amount of persistent intestinal fluid excretion |
| Dysphagia            | Clinical observation only; intervention not indicated | Enteral/intravenous nutrition (Including TPN) indicated | Medical intervention under local anesthesia indicated (e.g., tracheal puncture, endoscopic gastrostomy) | Intervention under general anesthesia indicated | – | – | Death | Gastrostomy |
| Intestinal fistula   | Clinical observation or diagnostic evaluation only; intervention not indicated (drainage only through existing drainage tube) | Medical management indicated (e.g., antibiotics) | Image-guided drain placement/paracentesis including drain replacement indicated | Intervention under general anesthesia indicated (colostomy) | At least one organ failure (e.g., pulmonary disorders requiring mechanical ventilation or renal disorders indicating dialysis) | Sepsis or multiple organ failure | Death | Persistent enterocutaneous fistula |
| Intestinal ischemia/ necrosis | Clinical observation or diagnostic evaluation only; intervention not indicated | Medical management indicated (e.g., antibiotics) | Radiological intervention/endoscopic/surgical intervention without general anesthesia indicated | Intervention under general anesthesia indicated (e.g., intestinal resection) | At least one organ failure (e.g., pulmonary disorders requiring mechanical ventilation or renal disorders indicating dialysis) | Sepsis or multiple organ failure | Death | Home enteral/intravenous nutrition |
| Gastric tube necrosis | Observation of a small fistula with oral contrast study or drainage imaging (drainage only through existing drainage tube) | Medical management (e.g., antibiotics), enteral/intravenous nutrition indicated | Radiological intervention/endoscopic/elective surgical intervention without general anesthesia indicated, including drain replacement | Intervention under general anesthesia indicated | At least one organ failure (e.g., pulmonary disorders requiring mechanical ventilation or nephropathy indicating dialysis) | Sepsis or multiple organ failure | Death | |
| Principle of grading                  | I                                      | II                                      | IIIa                              | IIIb                              | IVa                                      | IVb                                      | V                                      | Supplemental explanation of suffix “d” |
|--------------------------------------|---------------------------------------|---------------------------------------|-----------------------------------|-----------------------------------|----------------------------------------|----------------------------------------|---------------------------------------|----------------------------------------|
| Reflux esophagitis                   | Clinical observation or diagnostic evaluation only; intervention not indicated | Medical management (e.g., PPI, pancreatic enzyme inactivators) or enteral/intravenous nutrition indicated | –                                 | Intervention under general anesthesia indicated | –                                      | –                                      | Death                                 | Persistent heartburn                   |
| Ileus (paralytic)                    | Clinical observation or diagnostic evaluation only; medical management not indicated except for laxatives and intravenous nutrition | Medical management beyond laxatives, NG tube placement, or intravenous nutrition management indicated | Nasoenteric tube placement        | Treatment for ileus under general anesthesia (with or without intestinal resection) | Extensive intestinal necrosis, at least one organ failure (e.g., pulmonary disorders requiring mechanical ventilation or nephropathy indicating dialysis) | Sepsis or multiple organ failure        | Death                                 | Home intravenous nutrition             |
| Pancreatic fistula                    | On or after postoperative day 3, drainage fluid amylase level ≥3 times the upper limit of institutional criteria, but intervention not indicated | Medical management indicated (e.g., antibiotics), enteral/intravenous nutrition indicated | Image-guided drain placement/paracentesis including drain replacement indicated | Intervention under general anesthesia indicated | At least one organ failure (e.g., pulmonary disorders requiring mechanical ventilation or nephropathy indicating dialysis) | Sepsis or multiple organ failure        | Death                                 | Residual pancreatic pseudocyst on CT, occasional fever, or abdominal pain |
| Intestinal obstruction                | Clinical observation or diagnostic evaluation only; medical management not indicated except for laxatives and intravenous nutrition | Medical management beyond laxatives, NG tube placement, or intravenous nutrition management indicated | Nasoenteric tube placement        | Treatment for ileus under general anesthesia (with or without intestinal resection) | Extensive intestinal necrosis, at least one organ failure (e.g., pulmonary disorders requiring mechanical ventilation or nephropathy indicating dialysis) | Sepsis or multiple organ failure        | Death                                 | Home intravenous nutrition             |
| Delayed gastric emptying             | Clinical observation or diagnostic evaluation only; intervention not indicated | Medical management (e.g., peristalsis stimulating drugs), NG tube placement, enteral/intravenous nutrition indicated | –                                 | Intervention under general anesthesia indicated | –                                      | –                                      | Death                                 | Persistent postprandial nausea         |
Table 1 continued

| Principle of grading | I | II | IIIa | IIIb | IVa | IVb | V | Supplemental explanation of suffix “d” |
|----------------------|---|----|------|------|-----|-----|---|----------------------------------------|
| Dumping syndrome     | Clinical observation only; intervention not indicated | Medical management indicated | – | Intervention under general anesthesia indicated | – | – | Death | Persistent dumping symptom |
| Biliary fistula       | Clinical observation or diagnostic evaluation only; intervention not indicated (drainage only through existing drainage tube) | Medical management indicated (e.g., antibiotics) | Image-guided drain placement/paracentesis including drain replacement indicated | Intervention under general anesthesia indicated (drainage) | At least one organ failure (e.g., pulmonary disorders requiring mechanical ventilation or nephropathy indicating dialysis) | Sepsis or multiple organ failure | Death | Residual pseudocyst on CT; occasional fever or abdominal pain |
| Cholecystitis         | Clinical observation or diagnostic evaluation only; medical management not indicated except for cholangiography | Medical management beyond cholangiography indicated | Medical intervention under local anesthesia indicated (e.g., Percutaneous transhepatic gallbladder drainage) | Intervention under general anesthesia indicated (cholecystectomy) | At least one organ failure (e.g., pulmonary disorders requiring mechanical ventilation or nephropathy indicating dialysis) | Sepsis or multiple organ failure | Death | Occasional fever or abdominal pain |
| Gastrointestinal anastomotic leak | Only small fistula observed on oral contrast study or drainage imaging (drainage only through existing drainage tube) | Medical management (e.g., antibiotics) or enteral/intravenous nutrition (Including TPN) indicated | Image-guided drain placement/paracentesis including wound opening or drain replacement indicated | Intervention under general anesthesia indicated (e.g., suture, reanastomosis, bypass, drainage, colostomy) | At least one organ failure (e.g., pulmonary disorders requiring mechanical ventilation or nephropathy indicating dialysis) | Sepsis or multiple organ failure | Death | Home enteral/intravenous nutrition |
| Ureteric injury       | Clinical observation or diagnostic evaluation only; intervention not indicated | Medical management indicated (e.g., antibiotics) | Transurethral ureteral stent insertion or percutaneous nephrostomy | Intervention under general anesthesia indicated | Acute renal failure, hemodialysis | Sepsis or multiple organ failure | Death | Discharged with ureteral stent |
| Urethral injury       | Foley catheter placement | Medical management indicated (e.g., antibiotics) | Intervention under local or lumbar anesthesia indicated (e.g., percutaneous cystostomy) | Intervention under general anesthesia indicated | At least one organ failure (e.g., pulmonary disorders requiring mechanical ventilation or nephropathy indicating dialysis) | Sepsis or multiple organ failure | Death | Discharged with Foley catheter placement |
| Principle of grading | I | II | IIIa | IIIb | IVa | IVb | V | Supplemental explanation of suffix “d” |
|----------------------|---|----|------|------|-----|-----|---|---------------------------------------|
| Postoperative hemor- | Controllable with compression only | Blood transfusion or medical management indicated | Surgical hemostasis under local anesthesia or endoscopic and radiological intervention hemostasis indicated | Intervention under general anesthesia indicated (hemostasis) | Single organ failure; stepdown ICU/ICU care indicated | Multiple organ failure; ICU/ICU management indicated | Death | Persistent anemia |
|rhage                 |               |                     |                               |                                    |                                |                                |   |                        |
| Seroma (Accumulation | Bedside paracentesis only (drainage only through existing drainage tube) | Image-guided drain placement/paracentesis including drain replacement indicated | Intervention under general anesthesia indicated | At least one organ failure (e.g., pulmonary disorders requiring mechanical ventilation or nephropathy indicating dialysis) | Sepsis or multiple organ failure | Death | Exudate leakage from wound, occasional fever and infection, discharged with drainage tube |
| Uterine anastomo- | Clinical or vaginal observation only; intervention not indicated | Medical management indicated (e.g., antibiotics) | Intervention under general anesthesia indicated (resuturing) | At least one organ failure (e.g., pulmonary disorders requiring mechanical ventilation or nephropathy indicating dialysis) | Sepsis or multiple organ failure | Death | Persistent leakage from uterovaginal anastomosis due to suture failure (surgical union of two different anatomical structures) |
| tic leak             |               |                   |                                |                                    |                                |                                |   |                        |
| Abdominal incisional | Clinical observation only; intervention not indicated except for truss and NSAIDs | Medical management indicated beyond truss and NSAIDs indicated | Medical intervention under local anesthesia indicated | Intervention under general anesthesia indicated (mesh, fascial resuturing) | Extensive intestinal necrosis, at least one organ failure (e.g., pulmonary disorders requiring mechanical ventilation or nephropathy indicating dialysis) | Sepsis or multiple organ failure | Death | Intestinal prolapse upon increased intra-abdominal pressure |
| hernia               |               |                   |                                |                                    |                                    |                                |   |                        |
| Wound dehiscence    | Clinical observation only; intervention not indicated except for wound irrigation | Medical management indicated (e.g., antibiotics) | Medical intervention under local anesthesia indicated (e.g., resuturing) | Intervention under general anesthesia indicated (e.g., resuturing) | Extensive intestinal necrosis, at least one organ failure (e.g., pulmonary disorders requiring mechanical ventilation or nephropathy indicating dialysis) | Sepsis or multiple organ failure | Death | Discharged with significant wound dehiscence |
| Principle of grading | I | II | IIIa | IIIb | IVa | IVb | V | Supplemental explanation of suffix “d” |
|----------------------|---|----|------|------|-----|-----|---|----------------------------------------|
| **Gastrointestinal** | **II** | **IIIa** | **IIIb** | IVa | IVb | V | **Death** | **Frequent outpatient endoscopic dilatation** |
| anastomotic stenosis | Clinical observation or diagnostic evaluation only; intervention not indicated | Enteral/intravenous nutrition (Including TPN) indicated | Balloon dilatation, stenting, magnetic compression anastomosis | Intervention under general anesthesia indicated (e.g., reanastomosis, bypass) | – | – | – | – |
| | | | | | | | | |
| **Intraabdominal abscess** | Clinical observation or diagnostic evaluation only; intervention not indicated | Medical management indicated (e.g., antibiotics) | Image-guided drain placement/paracentesis including drain replacement indicated | Intervention under general anesthesia indicated (drainage) | At least one organ failure (e.g., pulmonary disorders requiring mechanical ventilation or nephropathy indicating dialysis) | Sepsis or multiple organ failure | Death | Residual abscess on CT, occasional fever or abdominal pain |
| | | | | | | | | |
| **Pelvic abscess** | Clinical observation or diagnostic evaluation only; intervention not indicated | Medical management indicated (e.g., antibiotics) | Image-guided drain placement/paracentesis including drain replacement indicated | Intervention under general anesthesia indicated (drainage) | At least one organ failure (e.g., pulmonary disorders requiring mechanical ventilation or nephropathy indicating dialysis) | Sepsis or multiple organ failure | Death | Residual abscess on CT, occasional fever or abdominal pain |
| | | | | | | | | |
| **Pneumonia** | Clinical observation or diagnostic evaluation only; intervention not indicated except for nebulizers, expectorants, or lung physiotherapy (e.g., postural drainage) | Medical management indicated (e.g., antibiotics) | Bronchoscopic aspiration, tracheal puncture | Tracheostomy under general anesthesia/sedation or mechanical ventilation | Mechanical ventilation indicated | Sepsis or multiple organ failure | Death | Persistent respiratory distress, occasional fever |
| | | | | | | | | |
| **Mediastinitis** | Clinical observation or diagnostic evaluation only; intervention not indicated | Medical management indicated (e.g., antibiotics) | Image-guided drain placement/paracentesis including drain replacement indicated | Intervention under general anesthesia indicated (drainage) | At least one organ failure (e.g., pulmonary disorders requiring mechanical ventilation or nephropathy indicating dialysis) | Sepsis or multiple organ failure | Death | Residual abscess on CT images, occasional fever or abdominal pain |
| | | | | | | | | |
| **Pyothorax** | Clinical observation or diagnostic evaluation only; intervention not indicated | Medical management indicated (e.g., antibiotics) | Image-guided drain placement/paracentesis including drain replacement indicated | Intervention under general anesthesia indicated (drainage) | At least one organ failure (e.g., pulmonary disorders requiring mechanical ventilation or nephropathy indicating dialysis) | Sepsis or multiple organ failure | Death | Residual abscess on CT images or discharged with tube drainage, open drainage |
### Table 1 continued

| Principle of grading | I | II | IIIa | IIIb | IVa | IVb | V | Supplemental explanation of suffix “d” |
|----------------------|---|----|------|------|-----|-----|---|-----------------------------------|
| **Lower extremity lymphangitis (Lymph node infection)** | Clinical observation or diagnostic evaluation only; intervention not indicated | Medical management indicated (e.g., antibiotics) | Medical intervention under local anesthesia indicated (lymphatic anastomosis) | Intervention under general anesthesia indicated (lymphatic anastomosis) | At least one organ failure (e.g., pulmonary disorders requiring mechanical ventilation or nephropathy indicating dialysis) | Sepsis or multiple organ failure | – | Persistent edema |
| **Infected lymphocele (Retroperitoneal abscess)** | Clinical observation or diagnostic evaluation only; intervention not indicated | Medical management indicated (e.g., antibiotics) | Drainage under local anesthesia or without anesthesia indicated | Intervention under general anesthesia indicated (incision and drainage) | At least one organ failure (e.g., pulmonary disorders requiring mechanical ventilation or nephropathy indicating dialysis) | Sepsis or multiple organ failure | Death | Residual abscess on imaging study, occasional fever or abdominal pain |
| **Infectious cervicitis** | Clinical or vaginal observation only; intervention not indicated | Medical management indicated (e.g., antibiotics) | Drainage under local anesthesia or without anesthesia indicated | Intervention under general anesthesia indicated (drainage, hysterectomy) | At least one organ failure (e.g., pulmonary disorders requiring mechanical ventilation or nephropathy indicating dialysis) | Sepsis or multiple organ failure | Death | Persistent infected vaginal discharge |
| **Uterine infection** | Clinical observation or diagnostic evaluation only; intervention not indicated | Medical management indicated (e.g., antibiotics) | Dilation and curettage under local anesthesia or without anesthesia indicated | Intervention under general anesthesia indicated (drainage, hysterectomy) | At least one organ failure (e.g., pulmonary disorders requiring mechanical ventilation or nephropathy indicating dialysis) | Sepsis or multiple organ failure | Death | Residual abscess on imaging study, occasional fever or abdominal pain |
| **Ovarian infection** | Clinical observation or diagnostic evaluation only; intervention not indicated | Medical management indicated (e.g., antibiotics) | Paracentesis drainage under local anesthesia indicated | Intervention under general anesthesia indicated (drainage, oophorectomy) | At least one organ failure (e.g., pulmonary disorders requiring mechanical ventilation or nephropathy indicating dialysis) | Sepsis or multiple organ failure | Death | Residual abscess on imaging study, occasional fever or abdominal pain |
| Principle of grading | I | II | IIIa | IIIb | IVa | IVb | V | Supplemental explanation of suffix “d” |
|----------------------|---|----|------|------|-----|-----|---|----------------------------------------|
| **Vulval infection** | Clinical observation or diagnostic evaluation only; intervention not indicated | Medical management indicated (e.g., antibiotics) | Paracentesis drainage under local anesthesia indicated | Intervention under general anesthesia indicated (drainage, skin flap, or musculocutaneous flap) | At least one organ failure (e.g., pulmonary disorders requiring mechanical ventilation or nephropathy indicating dialysis) | Sepsis or multiple organ failure | Death | Residual abscess on imaging study, occasional fever or abdominal pain |
| **Wound infection** | Clinical observation or diagnostic evaluation only; intervention not indicated, except for wound opening and wound irrigation at the bedside | Medical management indicated (e.g., antibiotics) | Medical intervention under local anesthesia indicated (e.g., drainage) | Intervention under general anesthesia indicated (e.g., drainage, resuturing) | At least one organ failure (e.g., pulmonary disorders requiring mechanical ventilation or nephropathy indicating dialysis) | Sepsis or multiple organ failure | Death | Continued outpatient irrigation |
| **Implant infection** | Clinical observation or diagnostic evaluation only; intervention not indicated | Medical management indicated (e.g., antibiotics) | Medical intervention under local anesthesia indicated (e.g., incision and drainage, implant removal) | Intervention under general anesthesia indicated (implant removal) | At least one organ failure (e.g., pulmonary disorders requiring mechanical ventilation or nephropathy indicating dialysis) | Sepsis or multiple organ failure | Death | Discharged with drainage tube placement; persistent infection |
| **Bladder injury** | Foley catheter placement indicated | Medical management indicated (e.g., antibiotics) | – | Intervention under general anesthesia indicated | At least one organ failure (e.g., pulmonary disorders requiring mechanical ventilation or nephropathy indicating dialysis) | Sepsis or multiple organ failure | Death | Discharged with Foley catheter placement |
| **Urinary incontinence** | Intermittent catheterization or Foley catheter placement indicated | Medical management indicated (e.g., anticholinergics) | Intervention under local or lumbar anesthesia indicated (e.g., clamp, collagen injection) | Intervention under general anesthesia indicated (e.g., artificial urinary sphincter) | Acute renal failure, hemodialysis | Sepsis or multiple organ failure | Death | Persistent condition requiring Intermittent catheterization; Discharged with Foley catheter placement |
| Table 1 continued |
|-------------------|
| Principle of grading |
| I | II | IIIa | IIIb | IVa | IVb | V | Supplemental explanation of suffix “d” |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Residual urine/Urinary retention | Intermittent catheterization or Foley catheter placement indicated | Medical management indicated (e.g., cholinergics) | Intervention under local or lumbar anesthesia indicated (e.g., endoscopic treatment, urethral dilatation) | Intervention under general anesthesia indicated (e.g., fistula closure) | Acute renal failure, hemodialysis | Sepsis or multiple organ failure | Death | Persistent condition requiring intermittent catheterization; Discharged with Foley catheter placement |
| Dyspareunia | Discomfort associated with vaginal penetration; intervention not indicated | Estrogen administration indicated | Medical intervention under local anesthesia indicated | Intervention under general anesthesia indicated | – | – | – | Persistent pain associated with sexual intercourse, persistent dyspareunia |
| Erectile dysfunction | Erectile dysfunction; intervention not indicated, except for external vacuum device for managing erectile dysfunction | Medical management indicated (e.g., Phosphodiesterase 5 inhibitors or intracavernosal injection of vasoactive agonists) | Intervention under local or lumbar anesthesia indicated | Intervention under general anesthesia indicated (e.g., penile prosthesis) | – | – | – | Persistent erectile dysfunction |
| Cervical atresia (uterine atresia) | Clinical or vaginal observation only; intervention not indicated | Associated with dysmenorrhea; medical management indicated (e.g., analgesics) | Bougienage of cervical duct with or without local anesthesia indicated | Intervention under general anesthesia indicated (cervical dilatation) | – | – | – | Persistent stenosis of the cervical os |
| Vaginal fistula | Clinical or vaginal observation only; intervention not indicated | Medical management indicated (e.g., antibiotics) | – | Intervention under general anesthesia indicated (vaginal fistula closure, colostomy) | At least one organ failure (e.g., pulmonary disorders requiring mechanical ventilation or nephropathy indicating dialysis) | Sepsis or multiple organ failure | Death | Persistent leakage from vagina |
| Ovarian deficiency syndrome | Clinical observation or diagnostic evaluation only; intervention not indicated | Medical management indicated (e.g., hormone replacement therapy) | – | – | – | Death | Hot flash requiring continued hormone replacement therapy, depression requiring continued psychiatric care |
Table 1 continued

| Principle of grading | I | II | IIIa | IIIb | IVa | IVb | V | Supplemental explanation of suffix “d” |
|----------------------|---|----|-----|-----|-----|-----|---|---------------------------------------|
| **Cervical chylous leakage** | Observation of chylous drainage fluid or paracentesis fluid only; intervention not indicated (drainage only through existing drainage tube) | Fat-restricted diet, intravenous nutrition indicated | Image-guided drain placement/paracentesis including drain replacement indicated | Intervention under general anesthesia indicated | – | – | Death | Persistent sensation of pressure in the neck |
| **Serous leakage** | Clinical observation only; intervention not indicated (drainage only through existing drainage tube) | Medical management indicated (e.g., antibiotics) | Image-guided drain placement/paracentesis including drain replacement indicated | Intervention under general anesthesia indicated | At least one organ failure (e.g., pulmonary disorders requiring mechanical ventilation or nephropathy indicating dialysis) | Sepsis or multiple organ failure | Death | Exudate leakage from the wound, occasional fever and infection, discharged with drainage tube |
| **Chylous ascites** | Observation of chylous drainage fluid or paracentesis fluid only; intervention not indicated (drainage only through existing drainage tube) | Fat-restricted diet, intravenous nutrition indicated | Image-guided drain placement/paracentesis including drain replacement indicated | Intervention under general anesthesia indicated | – | – | Death | Persistent abdominal fullness |
| **Subcutaneous phlebitis (Mondor disease)** | Clinical observation or diagnostic evaluation only; intervention not indicated except for NSAIDs | Opioid administration, or treatment by pain control specialist indicated | Medical intervention under local anesthesia indicated | Intervention under general anesthesia indicated | – | – | – | Surgical site subcutaneous phlebitis; cord-like mass |
| **Thrombosis/embolism** | Clinical observation or diagnostic evaluation only; intervention not indicated | Medical management indicated (e.g., anticoagulants) | Invasive treatment indicated (e.g., thrombus ablation via catheter, IVC filter) | Intervention under general anesthesia indicated (pulmonary artery thrombectomy) | Single organ failure caused by thromboembolism (e.g., lung, brain, heart) | Multiple organ failure caused by thromboembolism (e.g., lung, brain, heart) | Death | Dyspnea following pulmonary infarction, paralysis following cerebral infarction |
| **Restricted shoulder joint range of motion** | Clinical observation only; intervention not indicated except for NSAIDs | Opioid administration, or treatment by pain control specialist indicated | Surgical intervention without general anesthesia indicated (e.g., nerve block) | Intervention under general anesthesia indicated | – | – | – | Continued restriction in the range of motion of the shoulder joint |
| Principle of grading | I | II | IIIa | IIIb | IVa | IVb | V | Supplemental explanation of suffix “d” |
|----------------------|---|----|------|------|-----|-----|---|--------------------------------------|
| **Fat necrosis**     |   |    |      |      |     |     |   | - Wound fat necrosis, occasional cicatrization, fever or infection |
| Clinical observation or diagnostic evaluation only; intervention not indicated except for wound opening and wound irrigation at the bedside | Medical management indicated (e.g., antibiotics) | Medical intervention under local anesthesia indicated (e.g., incision and drainage) | Intervention under general anesthesia indicated | At least one organ failure (e.g., pulmonary disorders requiring mechanical ventilation or nephropathy indicating dialysis) | Sepsis or multiple organ failure | Death | - |
| **Skin necrosis (flap necrosis)** |   |    |      |      |     |     |   | - Insufficient epithelialization, persistent infection |
| Clinical observation or diagnostic evaluation only; intervention not indicated | Medical management indicated (e.g., antibiotics) | Medical intervention under local anesthesia indicated (e.g., debridement, skin grafting) | Intervention under general anesthesia indicated (skin grafting) | At least one organ failure (e.g., pulmonary disorders requiring mechanical ventilation or nephropathy indicating dialysis) | Sepsis or multiple organ failure | Death | - |
| **Subcutaneous emphysema** |   |    |      |      |     |     |   | - Discharged with subcutaneous air accumulation |
| Clinical observation or diagnostic evaluation only; intervention not indicated except for subcutaneous puncture and compression with breast band at the bedside | Medical management indicated (e.g., antibiotics) | Radiological intervention treatment without general anesthesia indicated (e.g., subcutaneous drain insertion) | Intervention under general anesthesia indicated | At least one organ failure (e.g., pulmonary disorders requiring mechanical ventilation or nephropathy indicating dialysis) | Sepsis or multiple organ failure | Death | - |
| **Upper extremity edema** |   |    |      |      |     |     |   | - Continued elastic stocking use |
| Intervention not indicated except for lymphatic massage and elastic stockings | Medical management indicated (e.g., diuretics) | Intervention under local anesthesia indicated (lymphatic anastomosis) | Intervention under general anesthesia indicated (lymphatic anastomosis) | At least one organ failure (e.g., pulmonary disorders requiring mechanical ventilation or nephropathy indicating dialysis) | Sepsis or multiple organ failure | Death | - |
| **Lower extremity lymphedema** |   |    |      |      |     |     |   | - Continued elastic stocking use |
| (edema of the extremities, lymphedema, localized edema) | Intervention not indicated except for lymphatic massage and elastic stockings | Medical management indicated (e.g., diuretics) | Intervention under local anesthesia indicated (lymphatic anastomosis) | Intervention under general anesthesia indicated (lymphatic anastomosis) | At least one organ failure (e.g., pulmonary disorders requiring mechanical ventilation or nephropathy indicating dialysis) | Sepsis or multiple organ failure | Death | - |
| **Obturator/femoral neuropathy** |   |    |      |      |     |     |   | - Persistent restriction in lower extremity adduction |
| (Gait disturbance) | Intervention not indicated except for walking aid and rehabilitation | Medical management indicated (e.g., vitamins) | Intervention under general anesthesia indicated (e.g., nerve suture) | At least one organ failure (e.g., pulmonary disorders requiring mechanical ventilation or nephropathy indicating dialysis) | Sepsis or multiple organ failure | Death | - |
### Table 1 continued

| Principle of grading | I | II | IIIa | IIIb | IVa | IVb | V | Supplemental explanation of suffix “d” |
|----------------------|---|----|------|------|-----|-----|---|----------------------------------------|
| **Wound pain**       |   |    |      |      |     |     |   | Home pain control                      |
| Clinical observation only; intervention not indicated except for NSAIDs | | | | | | | | |
| Opioid administration, or treatment by pain control specialist indicated | | | | | | | | |
| Surgical intervention indicated (e.g., nerve block) | | | | | | | | |
| **Others (No AE term)** |   |    |      |      |     |     |   | |
| Deviation from normal postoperative course. Medication, surgical intervention, endoscopic treatment, or radiological intervention treatment not indicated | | | | | | | | |
| Treatment with antiemetics, antipyretics, analgesics, or diuretics; electrolyte replenishment; or physical therapy is not included in this category (even if these treatments are indicated, the condition is categorized as Grade I); open wound infection at the bedside is Grade I | | | | | | | | |
| Medication indicated except for antiemetics, antipyretics, analgesics, and diuretics | | | | | | | | |
| Surgical, endoscopic, or radiological intervention treatment indicated (without general anesthesia) | | | | | | | | |
| IC/ICU management indicated; life-threatening complications (including complications in the central nervous system) AND single organ failure (including dialysis) | | | | | | | | |
| IC/ICU management indicated; life-threatening complications (including complications in the central nervous system) AND multiple organ failure | | | | | | | | |
| Death | | | | | | | | |

IC, intermediate care; ICU, intensive care unit; TPN, total parenteral nutrition; PPI, proton pump inhibitor; NG tube, nasogastric tube; CT, computed tomography.
more widely used. One controversial issue is that AE terms are not well defined and different AE terms designate the same AEs in different clinical trials. For example, when intestinal obstruction occurs, some investigators could report this AE as “ileus”, but others refer to it as “small bowel obstruction” or “colon obstruction”. Under such circumstances, the incidence of this AE cannot be counted accurately. A second issue is that only general grading criteria are defined and therefore, grading can be difficult in some cases and subject to bias by the grader. For example, primary non-operative treatment for intestinal obstruction is gastroenteric tube decompression. Nasogastric tube or nasoenteric tube is utilized depending on the severity, but the original Clavien-Dindo classification does not define what grading should be applied for any type of gastroenteric tube placement for decompression.

The JCOG PC criteria were established to address these issues. The advantages of the JCOG PC criteria are as follows: First, commonly experienced surgical AEs are specified and listed. To compare precisely the frequency of surgical complications between studies, use of the common AE terms specified in the JCOG PC criteria is recommended. Second, grading definitions are straightforward and optimized for surgical complications. With these advantages, the JCOG recommends that the JCOG PC criteria be used to supplement the Clavien-Dindo classification, while maintaining the overall Clavien-Dindo classification. In JCOG, some disease-oriented subgroups are conducting clinical trials including surgery and using both the CTCAE and JCOG PC criteria to evaluate postoperative complications. After these trials are completed, we will evaluate the concordance between the grading by the CTCAE and that by the JCOG PC criteria. We also plan to explore the advantages and disadvantages of the JCOG PC criteria.

The JCOG PC criteria have some limitations. First, these AE terms were chosen somewhat arbitrarily, but by experienced surgeons, and specific grading was decided based on the opinions and experience of our committee members. A second limitation of the JCOG PC criteria is that they do not include intraoperative complications. Our intent was to further define and clarify the criteria of the Clavien-Dindo classification and we considered that incorporating intraoperative complications would deviate too much from the original concept. Another common classification may be required to define and grade intraoperative complications. A third limitation is that all descriptions in the Clavien-Dindo classification pertain to early postoperative complications. Here, ‘early postoperative’ generally indicates the time from surgery to the first hospital discharge, but in theory, the Clavien-Dindo classification can be applied broadly to late postoperative complications after hospital discharge. Within this context, the JCOG PC criteria are mainly intended to be used for early postoperative complications, but they can also be used after hospital discharge, although would require more definitions and AEs.

In conclusion, the goals of the JCOG PC criteria are to standardize the AE terms used for early postoperative complications by providing more detailed grading guidelines based on the Clavien-Dindo classification. We suggest that researchers use the JCOG PC criteria in every surgical trial to allow for precise comparison of the frequency of surgical complications among trials.

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Compliance with ethical standards

Conflict of interest Hiroshi Katayama and his coauthors declare no conflicts of interest regarding this research.

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