Standardizing Clinical End Points in Aortic Arch Surgery
A Consensus Statement From the International Aortic Arch Surgery Study Group

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Since the introduction of hypothermic circulatory arrest for aortic arch surgery in 1975,1 there has been considerable progress in addressing this complex surgical pathology.2–4 However, the rapidity with which operative techniques have evolved has outpaced methodical appraisal of their clinical merit, leaving behind a wealth of perfunctory data. In particular, existing emphasis on neurological outcomes has neglected other critical end points, whereas inconsistent definitions and reporting formats limit the applicability of the results of some studies. Robust comparisons between institutional reports are therefore difficult, restricting critical appraisal and summary of existing surgical approaches.

The International Aortic Arch Surgery Study Group (IAASSG) has been formed to enable multi-institutional collaboration to better explore the impact of surgical techniques on patient outcomes, using uniform definitions of events and clinical end points. A key endeavor is to standardize reporting formats to facilitate effective comparisons. Such a concerted effort, with the combined expertise of leading academic surgeons, paves the way for a unified language specific for aortic arch surgery that promotes closer cooperation and systematic evaluation and is essential in forming a framework of existing knowledge and guiding progress and research for the future.5,6

The IAASSG has devised a management-oriented classification system for significant clinical end points specific for aortic arch surgery and has undertaken a consensus survey of leading arch surgeons. The following report describes this classification scheme and reports the results of the consensus.

Methodology
Rationales of the Grading System

A management-oriented classification system for complications, which grades adverse events by severity on the basis of the management required, is simple, reproducible, and comprehensive.7 It avoids duplication of overlapping results and limits the fluctuating ratings of negative outcomes between institutions by providing standardized definitions.7,8 Stratifying the severity of relevant complications into grades allows more thorough analysis to be achieved to assist benchmarking of existing procedures, identifying areas in need of improvement, guiding prospective research, and evaluating the effectiveness of interventions. Such an approach has been used widely7 and has been successfully validated by several subspecialties and procedures.9–14 Variants of this approach have also been implemented for thoracic surgery, resulting in a feasible system that facilitates objective assessments and identifies the burden of individual complications.15,16

Following the work by Dindo and coworkers,7 we propose the following system for grading adverse outcomes specific for aortic arch surgery (Table 1). Clinical complications are stratified into 5 major grades, from those that are self-limiting or
Principles for Selecting and Defining Clinical End Points

The selection of relevant clinical end points and the establishment of the classification scheme were done according to the following criteria:

1. Included clinical end points must be pertinent to aortic arch surgery.
2. Clinical end points must have the capacity to be altered by varying elements of surgical practice.
3. Definitions must be consistent with existing surgical literature and applicable to retrospective data.
4. Classifications must represent clinical management that is aligned with the severity of pathophysiological mechanisms.
5. Classifications must be sufficiently simple and robust to encourage compliance and reporting.

A systematic review of the current literature for prognostic factors was performed using 6 electronic databases—Ovid Medline, EMBASE, ACP Journal Club, Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trials, and Database of Abstracts of Review of Effectiveness—from January 1985 to March 2013. To maximize the sensitivity of the search, “aortic arch surgery” or “aneurysm, dissecting” or “aorta, thoracic” or “aortic aneurysm” and “circularity arrest” or “circularity arrest, deep hypothermia induced” were included as key words or MeSH terms. Original studies that included patient cohorts of at least 100 patients were identified. Significant prognostic factors on univariate and multivariate analyses were tabulated.

Guided by these results and the above criteria, 15 clinical end points from 6 major systems were deemed pertinent for aortic arch surgery and therefore graded according to their clinical manifestations, time course and severity, and treatment provided. These 6 major systems include neurological, cardiovascular, respiratory, renal, gastrointestinal, and other systems. The selected end points include all the surgical complications identified by a consensus guideline on the diagnosis and management of thoracic aortic disease published between the American College of Cardiology Foundation, American Heart Association, American Association for Thoracic Surgery, and others.17

Consensus Survey Process

To evaluate the acceptance of the proposed clinical end-point classification system, a panel of expert aortic surgeons was formed by identifying institutions in which surgeons have published >100 aortic arch surgical cases. The chief surgeons who performed these operations were contacted. Overall, a panel of 53 experts was identified.

An individualized e-mail invitation was sent to the panel of experts, with a link to a secure Web site that presented the classification system and the current level of evidence. Participants were asked whether “the proposed classification scheme includes the minimal set of clinical end points required” for each of the 6 systems, as well as if they agree with a management-based classification system and if they believe the entire classification scheme is reproducible, logical, useful, or comprehensive. Voting took place in May 2013, and anonymous responses to the questions were tabulated into a centralized database. Consensus was defined a priori as >80% agreement among the panel of experts.

Results

Proposed Classification of Clinical End Points

Neurological System

The neurological system consists of 3 minimum compulsory clinical end points: global neurological deficit, focal neurological deficit, and spinal neurological deficit.
Table 3. Classifications of Clinical End Points of the Cardiovascular System

<table>
<thead>
<tr>
<th>Cardiovascular System</th>
<th>Grade I</th>
<th>Grade II</th>
<th>Grade III</th>
<th>Grade IV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Myocardial ischemia</td>
<td>No intervention required</td>
<td>Requiring pharmacological therapy</td>
<td>Requiring diagnostic angiography with or without percutaneous coronary intervention</td>
<td>Requiring surgical intervention for revascularization</td>
</tr>
<tr>
<td>Low cardiac output syndrome</td>
<td>Requiring volume adjustment to optimize preload</td>
<td>Requiring pharmacological therapy</td>
<td>Requiring intra-aortic balloon pump insertion</td>
<td>Requiring extracorporeal membrane oxygenation support or requiring surgical intervention under general anesthesia or requiring ventricular assist device</td>
</tr>
<tr>
<td>Arrhythmia</td>
<td>Transient non–life-threatening atrial or ventricular arrhythmia, self-limiting</td>
<td>Non–life-threatening arrhythmia, requiring antiarrhythmic medications or anticoagulation therapy</td>
<td>Non–life-threatening arrhythmia affecting hemodynamic status, requiring DC cardioversion or temporary pacing</td>
<td>Arrhythmia, requiring a permanent pacemaker or defibrillator insertion, or life-threatening arrhythmia, requiring DC cardioversion or pacing</td>
</tr>
<tr>
<td>Pericardial effusion</td>
<td>Without clinical or echocardiographic features of tamponade, self-limiting</td>
<td>Without features of tamponade, requiring pharmacological therapy</td>
<td>Causing tamponade, requiring percutaneous drainage (not related to active bleeding)</td>
<td>Causing tamponade, requiring surgical intervention (not related to active bleeding)</td>
</tr>
</tbody>
</table>

Since the mid-1970s, temporary and permanent neurological deficits have remained the principal morbidity outcome of interest after arch surgery. Temporary neurological deficit has been defined as a short-term global deficit or as a short-term clinical manifestations of neurocognitive decline (such as confusion, agitation, delirium, obtundation, or Parkinsonism) without localized signs 
and is associated with long-term functional deficits and decline in quality of life. Permanent neurological deficit has been defined as either focal (embolic stroke) or global (diffuse coma) deficits with permanence that persists at discharge, and is a recognized predictor for mortality.

However, in the current literature, the clinical severity of temporary and permanent neurological deficits is rarely reported, and significant variations exist in their definitions. Such classification also does not differentiate between the underlying pathophysiology, nor does it embrace all the clinical manifestations of neurological complications. For instance, transient focal neurological deficits would not fit in the category of either temporary or permanent neurological deficits. To overcome these deficiencies, we propose that neurological complications be classified first as either global or focal events and then by severity and chronicity, as outlined in Table 2. Global neurological deficit is manifested as postoperative agitation, delirium, obtundation, or myoclonic movements, without localized cerebral neurological signs. Focal neurological deficit is manifested as lateralizing sensory or motor deficit or focal seizure activity.

Spinal neurological complication is a key clinical end point that has been inadequately reported in the past. However, with a growing trend for using warmer hypothermic temperatures for circulatory arrest, the spinal cord may become more vulnerable to ischemic damage and therefore must be included as a compulsory clinical end point in arch surgery.

Cardiovascular System

The cardiovascular system consists of 4 minimum compulsory clinical end points: myocardial ischemia, low cardiac output syndrome, arrhythmia, and pericardial effusion (Table 3).

The complexities of arch surgery and coexisting cardiovascular risk factors may negatively affect patient outcomes. Myocardial ischemia, as evidenced by new ST-T changes, local-regional wall abnormality, elevated biomarkers, or symptoms and signs, is an important cause of perioperative death after arch surgery, as are low cardiac output syndrome and arrhythmias. Low cardiac output syndrome is classified according to the therapy provided, consistent with other studies. Pericardial effusion is a frequent complication after cardiac surgery and can be life-threatening, causing tamponade and death. These particular adverse events are regarded as minimum compulsory cardiovascular clinical

Table 4. Classifications of Clinical End Points of the Respiratory System

<table>
<thead>
<tr>
<th>Respiratory System</th>
<th>Grade I</th>
<th>Grade II</th>
<th>Grade III</th>
<th>Grade IV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parenchymal complications</td>
<td>Atelectasis, requiring high-flow supplemental oxygen or self-limiting within 24 h</td>
<td>Pneumonia, requiring antibiotic therapy, or pulmonary edema, requiring diuretics, or requiring intubation for 24 to 72 h</td>
<td>Atelectasis, pneumonia, pulmonary edema, or acute lung injury, requiring noninvasive ventilation, or requiring intubation for 3 to 7 d</td>
<td>Atelectasis, pneumonia, pulmonary edema, or acute respiratory distress syndrome, requiring mechanical ventilation, or requiring intubation for &gt;7 d or tracheostomy</td>
</tr>
<tr>
<td>Pleural complications</td>
<td>Small pneumothorax or pleural effusion requiring high-flow supplemental oxygen</td>
<td>Pleural effusion requiring diuretics</td>
<td>Pneumothorax or pleural effusion, requiring insertion of intercostal drain</td>
<td>Life-threatening tension pneumothorax, requiring urgent insertion of intercostal drain, or parapneumonic effusion or post-hemorrhagic pleural collection, requiring surgical intervention</td>
</tr>
</tbody>
</table>
end points for arch surgery, which also mirror complications reported in large-scale cardiac databases.28

**Respiratory System**

The respiratory system consists of 2 minimum compulsory clinical end points: parenchymal and pleural complications (Table 4).

The most frequently occurring adverse events related to the lung parenchyma after aortic arch surgery and deep hypothermic circulatory arrest include atelectasis, pneumonia, pulmonary edema, and acute respiratory distress syndrome. The common adverse events affecting the pleural space include pneumothorax and pleural effusion. Such classification reflects the underlying pathophysiology of the events, which dictates treatment options. These adverse events have been associated with mortality on univariate and multivariate analyses in several studies23,22,29–33 and therefore are included as compulsory respiratory system clinical end points.

**Renal System**

Renal dysfunction is a significant and frequent predictor for mortality after aortic arch surgery.23,24,29–33 Despite their prevalence, renal complications are inconsistently reported. Some studies associate renal dysfunction with creatinine levels,29,34,35 whereas others define it according to urine output24 or use of dialysis.36 Many other studies only perfunctorily mention renal dysfunction or failure without providing a clear definition.21,32,37,38 There is a clear need for standardized assessment of postoperative renal function.

The RIFLE (risk, injury, failure, loss of kidney function, end-stage kidney disease) classification was introduced in 2004 to quantify the functional severity of acute kidney injury using biomarkers and clinical measurements,39 with 3 grades of increasing severity of acute kidney injury (risk, injury, failure) and 2 outcome classes (loss, end-stage kidney dysfunction). It is a simple, readily available clinical tool that has been widely used in intensive care and correlates progressive increases in mortality with worsening RIFLE classes.40,41 In cardiac and aortic arch surgery, a strong association between RIFLE classification and mortality has been consistently demonstrated.42–44 The IAASSG supports adopting the RIFLE classification as a measure of postoperative kidney dysfunction (Table 5). This will capture subtle changes in renal function, which may have a significant impact on risk for subsequent mortality.45

**Gastrointestinal System**

Gastrointestinal complications have been reported in 3.0% to 9.6% of arch surgeries21,23,46 and have been identified as a significant predictor for hospital death.23,30,33 Similarly, hepatic complications have been reported in up to 14.5% of patients.23 It is proposed that visceral hypoperfusion is a cause of gastrointestinal complications after cardiac surgery47; therefore, it is crucial to carefully evaluate the impact of hypothermic circulatory arrest and duration of warm ischemic time on gut and hepatobiliary complications after aortic arch surgery (Table 6).

**Other Systems**

Typical surgical complications are often exacerbated by the extensive physiological insult that is associated with hypothermic circulatory arrest. Clotting times are more significantly increased during hypothermia,48,49 whereas reoperation for bleeding in arch surgery has been reported as a predictor of mortality.22,23,30,31 An analysis of the German Registry for Acute Aortic Dissection Type A showed that bleeding complications have been reported in up to 25.9% of patients.50 Classification of bleeding complications was guided by 2 principles: the application of clinically objective markers and treatment protocol. Such stratification provides a clearly defined criterion that ensures consistency and easy applicability (Table 7).

**Mortality**

Perioperative all-cause mortality is an objective and practical measure for assessing absolute surgical outcome. Perioperative

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**Table 5. Classifications of Clinical End Points of the Renal System**

<table>
<thead>
<tr>
<th>Renal System</th>
<th>Grade I: Risk</th>
<th>Grade II: Injury</th>
<th>Grade III: Failure</th>
<th>Grade IV: Loss/End-Stage Kidney Dysfunction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Renal dysfunction (modified RIFLE classification)</td>
<td>Serum creatinine increased by &gt;1.5 times baseline values, GFR decreased by &gt;25%, or urine output &lt;0.5 mL·kg⁻¹·h⁻¹ for 6 h</td>
<td>Serum creatinine increased by 2–3 times the baseline values, GFR decreased by &gt;50%, or urine output &lt;0.5 mL·kg⁻¹·h⁻¹ for 12 h</td>
<td>Serum creatinine increased by &gt;3 times the baseline values, GFR decreased by &gt;75%, oliguria: urine output &lt;0.3 mL·kg⁻¹·h⁻¹ for 24 h, or anuria &gt;12 h or requiring temporary hemodialysis support for resolution</td>
<td>Complete loss of kidney function, requiring ongoing hemodialysis</td>
</tr>
</tbody>
</table>

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**Table 6. Classifications of Clinical End Points of the Gastrointestinal System**

<table>
<thead>
<tr>
<th>Gastrointestinal System</th>
<th>Grade I</th>
<th>Grade II</th>
<th>Grade III</th>
<th>Grade IV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gut complications</td>
<td>Ileus lasting &lt;48 h, self-limiting</td>
<td>Ileus lasting 48–72 h, requiring prokinetics medications</td>
<td>Prolonged ileus lasting &gt;72 h or gastric paresis, requiring nasogastric tube insertion, with or without total parental nutrition supplement; or gut ischemia manifested as metabolic acidosis or increased lactate, requiring general surgeon consultation</td>
<td>Gut ischemia, requiring surgical intervention</td>
</tr>
<tr>
<td>Hepatobiliary complications</td>
<td>Transient elevated hepatic enzymes by 1.5 times the upper range of normal &lt;48 h, self-limiting</td>
<td>Transient elevated hepatic enzymes by 1.5 times the upper range of normal &gt;48 h</td>
<td>Hepatobiliary ischemia manifested as metabolic acidosis or increased lactate or prothrombin time, requiring general surgeon consultation</td>
<td>Hepatobiliary ischemia, requiring surgical intervention</td>
</tr>
</tbody>
</table>
mortality is defined as death within the same hospital stay or within 30 days after the index procedure (if the patient was discharged before 30 days). It is classified according to the causal organ dysfunction (eg, grade V renal dysfunction).

**Consensus Results on Clinical End Points**
In the absence of standardized reporting of clinical end points, the IAASSG conducted a consensus survey on the systematic reporting of adverse events after aortic arch surgery using the grading system described above. The consensus process included anonymity of participants to avoid individual dominance.

Invitations were sent to 53 surgeons. Forty-five (85%) completed the survey, representing 40 centers from 12 countries (Figure 1). The remaining surgeons did not respond after 3 reminders were sent.

When respondents were asked whether the proposed classification scheme for each of the 6 systems included the minimal set of clinical end points required for reporting, agreement ranged between 93% (gastrointestinal) and 98% (neurological, cardiovascular, and renal systems; Figure 2). In addition, 98% of respondents agreed that a management-based classification system will facilitate the standardization of clinical end points and allow proper cross-comparisons among future clinical studies. Overall, 98% to 100% of respondents believe this system is reproducible, logical, and useful, and 91% believe it is comprehensive (Figure 3).

**Discussion**

The absence of standardized reporting of surgical complications significantly curtails the evaluation of operative strategies in aortic arch surgery. We have reached a consensus of 45 aortic arch surgeons from 40 institutions in 12 countries for reporting clinical outcomes in a logical and reproducible manner. This will encourage uniformity of definitions of adverse events in arch surgery, which will facilitate robust cross-comparisons among clinical studies. Such an endeavor is essential to the critical appraisal of surgical techniques and operative strategies because it forms the basis for large-scale collaborative research between institutions.

A management-based system has the benefit that it represents the most readily and objectively available information regarding a patient’s complications, can indicate the least invasive or least expensive resource required to manage a complication, and can reflect the extent of stress and further morbidity inflicted on the patient. Results from the present consensus survey indicate that such a standardized system is greatly merited in arch surgery, with 98% of respondents agreeing that it will enable cross-comparisons in future studies. Furthermore, 98% to 100% of respondents agree that the proposed classification

### Table 7. Classifications of Clinical End Points of Other Systems

<table>
<thead>
<tr>
<th>Other Systems</th>
<th>Grade I</th>
<th>Grade II</th>
<th>Grade III</th>
<th>Grade IV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Postoperative bleeding</td>
<td>Hemoglobin dropped &lt; 3 g/dL from baseline and no blood product transfusion required</td>
<td>Hemoglobin dropped as a result of bleeding &gt;3 g/dL from baseline; bleeding, requiring 1–3 U packed red blood cell; or bleeding, requiring 1 round of blood products (fresh-frozen plasma, cryoprecipitate, or platelets)</td>
<td>Bleeding, requiring ≥4 U packed red blood cell; bleeding, requiring ≥2 rounds of blood products (fresh-frozen plasma, cryoprecipitate, or platelets); or massive transfusion protocol activated or requiring recombinant factor VII</td>
<td>Bleeding causing hypovolemic shock or tamponade, requiring surgery; bleeding in a critical area or organ such as intracranial, intraspinal, or pericardial necessitating surgical intervention for resolution; or bleeding resulting in disseminated intravascular coagulopathy</td>
</tr>
<tr>
<td>Wound complications</td>
<td>Localized serous discharge from the wound without features of infection, self-limiting</td>
<td>Superficial wound infection or cellulitis, requiring antibiotics for resolution</td>
<td>Wound infection, requiring opening of the wound at the bedside, or wound dehiscence, requiring closing of the wound under local anesthetic or application of negative-pressure wound therapy</td>
<td>Deep wound infection involving the sternum, requiring surgical intervention under general anesthesia, or wound dehiscence requiring reapproximation of the sternum under general anesthesia</td>
</tr>
<tr>
<td>Infections (other than wound infections)</td>
<td>Positive microbiology without features of infection, self-limiting</td>
<td>Infection, requiring antibiotics for resolution</td>
<td>Infection, requiring surgical, endoscopic or radiological intervention without general anesthesia</td>
<td>Infection causing septic shock, requiring vasopressors and surgical intervention under general anesthesia, or infection, causing secondary organ dysfunction</td>
</tr>
<tr>
<td>Postoperative recurrent laryngeal nerve palsy</td>
<td>Transient hoarseness of voice, resolving within 72 h</td>
<td>Transient hoarseness of voice, resolving after 72 h</td>
<td>Hoarseness of voice with no signs of improvement at the time of discharge, reversible recurrent laryngeal nerve injury requiring injection, or vocal cord paresis confirmed by direct laryngoscopy</td>
<td>Aspiration secondary to recurrent laryngeal nerve injury, requiring nil by mouth or insertion of nasogastric tube; or irreversible recurrent laryngeal nerve injury, requiring permanent medialization or other surgical intervention</td>
</tr>
</tbody>
</table>

![Figure 1](http://circ.ahajournals.org/)

*Figure 1. Geographic representation of respondents: 45 experts completed the consensus survey, representing 40 centers from 12 countries.*
is reproducible, logical, and useful, reflective of the acceptability of other management-based grading systems. To better evaluate patient outcomes after aortic arch surgery, the IAASSG has initiated the ARCH Projects to overcome the deficiencies faced by the current literature. To date, over 30 academic institutions from 10 countries have contributed over 10,000 aortic arch cases to build an international clinical database. In addition to this ongoing retrospective database, which will assess the impact of varying surgical techniques on mortality and morbidity, identify predictors for neurological and operative risk, and formulate and validate risk predictor models, a multi-institutional prospective registry has been planned. By incorporating the present consensus of standardized clinical end points, these projects will generate more robust and comprehensive evaluations and comparisons of surgical outcomes.

Conclusions
The IAASSG has made major progress in standardizing reporting system for surgical complications in aortic arch surgery. This system amalgamates end points relevant to arch surgery with commonly used benchmarks to formulate a management-guided and pragmatic classification scheme. Such classification promotes consistent reporting, uniform definitions, and a reliable systematic appraisal of arch surgery. This will be the first, and perhaps most important, step in evaluating the progress achieved in aortic arch surgery over the past 30 years and will help guide future avenues of reporting and research.

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Disclosures
None.

References


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