Identifying and grading factors that modify the outcome of endovascular aortic aneurysm repair

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Prospective randomization is a fundamental feature of clinical trial design because this process provides a mechanism for equal distribution among treatment arms of all factors, both recognized and hidden, that might modify outcome. Although an acceptable substitute for randomization does not exist, in the area of endovascular therapy for abdominal aortic aneurysm, practical considerations often limit the use of randomization. In this regard, adjusting for case severity mix provides a mechanism to obtain some measure of confidence in comparing the outcomes of two or more treatment protocols pursued within a single clinical trial or reported by separate investigators. Relevant examples include comparing outcomes of two or more different devices undergoing separate clinical trials; analyzing results of the same technical approach reported by different investigators; and gauging the effect of an adjunctive measure, improved device, or enhanced deployment system. Thus, it would be inappropriate to compare the outcomes of endograft repair between two studies if one was populated with healthy patients and relatively small aneurysms and the other treated more complex aneurysms among patients with significant comorbidities. The objective of adjusting for case variability is best achieved with severity scoring schemes incorporating all factors known to affect the outcome being assessed. Although scoring schemes that attempt to define the severity of associated medical comorbidities and anatomic factors have been reported for lower-extremity peripheral vascular[1] and venous disease,[2] comparable systems that are appropriate for endovascular aneurysm repair have yet to be proposed. In this report, comorbidity and anatomic schemes are offered as an initial effort to develop useful tools for the comparative analysis of data related to endovascular treatment of aortic aneurysms.

A GENERAL APPROACH FOR CATEGORIZATION AND WEIGHTING OF DISEASE SEVERITY

Optimally the design of a disease severity scoring scheme should grade each of the factors known or generally presumed to affect the outcome of endovascular repair and combine these into an overall score. In principle, factors affecting outcome can be separated into the following two general groups: (1) anatomic factors that affect technical success (successful access, accurate deployment, complete exclusion) and its durability (freedom from endoleak and secondary procedures); and (2) medical comorbidities that influence systemic morbidity and initial and late mortality. There is an advantage to scoring these two sets of factors separately, so as to allow correlation with the reported rates of technical success, persistent or recurrent endoleak, and secondary intervention on the one hand, and morbidity and mortality rates on the other. Use of such schemes, however, dictates that factors be described in sufficient detail for use of uniform grades, such as the Society for Vascular Surgery/American Association for Vascular Surgery (SVS/AAVS) 0 to 3 scale corresponding to absent, mild, moderate, and severe. With the preceding considerations in mind, a Comorbity Severity Score and an Anatomic Factor Severity Score are proposed. *Scoring all of the factors affecting outcome may seem complex when viewed in toto, but in a given report, it is probably unnecessary for all scores to be included.* One need apply only those scores that pertain to the outcome measures being investigated and reported, particularly those that affect an outcome for which a significant difference is claimed. Nevertheless, all of the scoring schemes are included in this report for the advantage of collecting prospective data in a manner that facilitates later analysis.

RISK STRATIFICATION BASED UPON COMORBID MEDICAL CONDITIONS: A COMORBIDITY SEVERITY SCORE

Cardiac deaths, related primarily to coronary artery disease, dominate the early and late mortality rates for both open surgery and endovascular aneurysm repair, accounting for the majority of deaths. As a consequence, at least seven scoring systems have been developed for assessing the relationship of bundled clinical parameters as a measure of cardiac risk. For example, Eagle's five clinical "markers" of cardiac disease (age >70 years, diabetes, history or Q-wave

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Table I. SVS/AAVS medical comorbidity grading system

Score	*Description of score*
Major components	
Cardiac status	
0	Asymptomatic, with normal electrocardiogram
1	Asymptomatic but with either remote myocardial infarction by history (6 months), occult myocardial infarction by electrocardiogram, or fixed defect on dipyridamole thallium or similar scan
2	Any one of the following: stable angina, no angina but significant reversible perfusion defect on dipyridamole thallium scan, significant silent ischemia (1% of time) on Holter monitoring, ejection fraction 25% to 45%, controlled ectopy or asymptomatic arrhythmia, or history of congestive heart failure that is now well compensated
3	Any one of the following: unstable angina, symptomatic or poorly controlled ectopy/arrhythmia (chronic/recurrent), poorly compensated or recurrent congestive heart failure, ejection fraction less than 25%, myocardial infarction within 6 months
Pulmonary status	
0	Asymptomatic, normal chest radiograph, pulmonary function tests within 20% of predicted
1	Asymptomatic or mild dyspnea on exertion, mild chronic parenchymal radiograph changes, pulmonary function tests 65% to 80% of predicted
2	Between 1 and 3
3	Vital capacity less than 1.85 L, FEV_1 less than 1.2 L or less than 35% of predicted, maximal voluntary ventilation less than 50% of predicted, PCO_2 greater than 45 mm Hg, supplemental oxygen use medically necessary, or pulmonary hypertension
Renal status	
0	No known renal disease, normal serum creatinine level
1	Moderately elevated creatinine level, as high as 2.4 mg/dL
2	Creatinine level, 2.5 to 5.9 mg/dL
3	Creatinine level greater than 6.0 mg/dL, or on dialysis or with kidney transplant
Minor components	
Hypertension	
0	None (cutoff point, diastolic pressure usually lower than 90 mm Hg)
1	Controlled (cutoff point, diastolic pressure usually lower than 90 mm Hg) with single drug
2	Controlled with two drugs
3	Requires more than two drugs or is uncontrolled
Age	
0	<55 y
1	55-69 y
2	70-79 y
3	>80 y

evidence of previous myocardial infarction, prior congestive failure, history of angina pectoris) have proved useful in identifying high-risk patients but serve mainly to select patients for additional cardiac testing.[3,4] Moreover, in a study of 125 vascular surgery patients, Lette et al[5] found that, of seven published scoring systems and 18 individual clinical parameters, only diabetes and Detsky score correlated with postoperative cardiac morbidity and death. The limitation of these schemes and the need to account for multiple comorbid conditions led to the development of the APACHE score, which, unfortunately, has not been a valid predictor of operative mortality. Likewise, although the POSSUM system has been found to correlate with mortality in one vascular surgery unit, its complexity and use of intraprocedural data (eg, blood loss) have limited its usefulness as a predictive score. The strength of the American Society of Anesthesiology classification system lies in its simplicity; however, this scoring scheme has been faulted for its reliance, in part, on subjective parameters. Thus, a comorbidity severity score is recommended that represents a modification of a risk factor score that has been featured in prior SVS/AAVS reporting standards[1] and related reports (Table I). In this approach, each risk factor is graded and reported separately with a framework for combining the most significant factors into an overall global score.

DEFINITION, CATEGORIZATION, AND GRADING OF AN INITIAL CLINICAL STATE

As a principle, all conditions presumed to affect reported outcomes should be recorded and reported in any study or trial. The comorbidities and scoring systems are mainly intended to represent systemic factors that are likely to affect major morbidity and mortality associated with endovascular or surgical treatment of the aortic aneurysm. A 0 to 3 scale for grading factor severity from absent to severe offers uniformity and simplicity. Notably, the revised SVS/AAVS cardiac score combines elements of Eagle's scheme but has been modified to include the results of established screening tests, such as the dipyridamole thallium perfusion scan, Holter monitor, and ejection fraction. Pulmonary and renal disease have also been included in the calculation of a comorbidity score, because both contribute to procedure morbidity and mortality. Other risk factors that warrant inclusion are hypertension and age. With these in mind, a combined comorbidity severity scoring scheme based upon the summation of weighted risks is offered (Table II). Specifically, cardiac, pulmonary, and renal risk factors are considered major components, whereas hypertension and age are used as minor components. In recognition of the dominant role cardiac risk plays in both early

Table II. Combined medical comorbidity severity scoring scheme

Risk factor	*Weighting*	*Score*
Cardiac	×4	12
Pulmonary	×2	6
Renal	×2	6
Hypertension	×1	3
Age	×1	3
Maximum score*		30

*Divide by 10 to restore 3-point scale.

mortality and late mortality, the cardiac risk score is given a quadruple weighting, the pulmonary and renal scores are doubled, and the two "minor" components are singly weighted. The maximum allowable comorbidity severity score using this scheme is 30. Thus, scores can be divided by 10 to yield a comorbidity severity score on a 3-point scale, where, as previously stated, grades of 0 to 3 correspond to absent, mild, moderate, and severe. A similar approach has been applied throughout the anatomic scoring schemes that follow.

RISK STRATIFICATION BASED ON VASCULAR MORPHOLOGY: AN ANATOMIC FACTOR SEVERITY SCORE

Anatomic characteristics determine the degree of difficulty and potential success of all endovascular-based treatment strategies. Anatomy influences delivery and deployment of the endoprosthesis, intraoperative imaging, exclusion of the aneurysm, and durability of endograft attachment, as well as long-term device integrity. As such, anatomic and other local vascular factors are expected to correlate with technical success, endoleak rate, migration, conversion rate, and the need for secondary procedures. Thus, standards for reporting the initial morphologic state are required to compare and stratify outcomes. However, categorization and grading of morphology, above all, must balance a necessity for both detail and simplicity.

Rationale for grading system and task-specific categorization. The rationale for many of the parameters in the developed categorization and grading system is based primarily on suspected relationships between anatomy and a specific outcome. With this in mind, we have avoided the presentation of a scoring system that combines all aspects of vascular morphology into a single global score, because such an approach risks losing insight into those anatomic characteristics that are most critical for a given task or outcome. Thus, we present grading systems appropriate for the scoring of distinct anatomical segments, as well as discrete combinations of these scores relevant for tasks and outcomes specific to the endovascular treatment of aortic aneurysms (Table III). Finally, although anatomical assessment can be performed using angiography, duplex or intravascular ultrasound scanning, or magnetic resonance angiography, the proposed grading systems are based primarily on data derived from computed tomography imaging.

It should be emphasized that the inclusion of all parameters and grading scales is not practical or necessary for many reports that deal with endovascular treatment of aneurysms. However, such schemes and measures are important when making comparisons or drawing conclusions about specific aspects of endovascular repair that are known to be affected by a particular anatomic factor. Thus, the application of these schemes is necessarily selective. It is acknowledged that both grading systems and schemes have been derived on the basis of "best current opinion" and are not based on correlations with the appropriate outcomes using large databases. Thus, it is anticipated that correlations with outcome will follow as clinical investigators test these schemes. In turn, the data from these studies are expected to provide the basis for future modification of these schemes.

DEFINITION, GRADING, AND CATEGORIZATION OF AN INITIAL MORPHOLOGIC STATE

Aortic neck

Morphologic characteristics of the proximal aortic neck influence the effectiveness of aneurysm exclusion and the durability of endograft attachment.[6,7] The proximal aortic neck extends from the most caudal main renal artery to the onset of the aneurysm, whereas the distal aortic neck is defined as the segment of aorta between the aortic bifurcation and the caudal-most portion of the aneurysm. Because the intended site of endograft deployment may constitute only a portion of available aortic neck, the aortic neck grading scheme may be referenced to either a planned or actual deployment site depending upon the objectives of the investigation. For example, if the objective of the study is to compare early type I endoleak rates between two or more different devices or the technical success of the same device in the hands of different investigators, grading the available aortic neck for fixation or sealing on the basis of the planned deployment site is recommended. The technical success rates, as a consequence, would reflect both deployment accuracy and device performance. However, if the investigation is directed at examining long-term device stability or aneurysm exclusion after graft implantation, it is recommended that morphologic grading be performed of the actual deployment site. That is, scoring should be performed of the achieved length of aortic neck used for sealing and/or fixation. Schemes have appeared in which neck morphology is described in terms of taper, reverse taper, or bulging. Although the simplicity of this classification is appealing, we believe its applicability to grading anatomic severity is limited.

Definitions and scoring relevant to the aortic neck region. An aortic neck scoring system is derived from a consideration of several morphologic characteristics, including the following: neck length (L) and diameter (d), the angle between the flow axis of the suprarenal aorta and the infrarenal neck (α), the angle between the flow axis of the infrarenal neck and the body of the aneurysm (β), and the amount of thrombus and calcification that are present in the neck (Fig 1, *A*). The flow axis of the aneurysm is defined as the line running from the proximal portion of the aneurysm (or end of the aortic neck) to the aortic bifurcation.

Table III. Definition, grading, and categorization of an initial morphologic state

Attribute	*Absent = 0*	*Mild = 1*	*Moderate = 2*	*Severe = 3*
Aortic neck				
Length (L)	$L > 25$ mm	$15 < L < 25$ mm	$10 < L < 15$ mm	$L < 10$ mm
Diameter (d)	$d < 24$ mm	$24 < d < 26$ mm	$26 < d < 28$ mm	$d > 28$ mm
Angle	> 150°	150° < angle < 135°	135° < angle < 120°	Angle < 120°
Calcification/thrombus	< 25%	25-50%	> 50%	–
Aortic aneurysm				
Angulation and tortuosity				
Aortic tortuosity index (T)	$T < 1.05$	$1.05 < T < 1.15$	$1.15 < T < 1.2$	$T > 1.2$
Aortic angle (Φ)	160° to 180°	140° to 159°	120° to 139°	< 120°
Thrombus	0	< 25%	25%-50%	>50%
Aortic branch vessels	No vessels	1 lumbar/IMA	2 vessels $d < 4$ mm	2 vessels IMA $d > 4$ mm
Pelvic perfusion	Patent bilateral IIA	Single IIA occlusion	Single IIA occlusion Contralateral IIA > 50% stenosis	Bilateral IIA occlusion
Iliac artery				
Calcification	None	<25% vessel length	25%-50% vessel length	>50% vessel length
Diameter/occlusive disease	$d > 10$ mm No occlusive disease	$8 < d < 10$ mm No stenosis <7 mm diameter or >3 cm long	$7 < d < 8$ mm Focal stenosis <7 mm diameter and <3 cm in length	$d < 7$ mm Stenosis < 7 mm diameter and >3 cm in length More than one focal stenosis < 7 mm diameter
Angulation and tortuosity				
Iliac tortuosity index (τ)	$\tau < 1.25$	$1.25 < \tau < 1.5$	$1.5 < \tau < 1.6$	$\tau > 1.6$
Iliac angle (ϕ)	160° to 180°	121° to 159°	90° to 120°	< 90°
Iliac artery sealing zone				
Length (L)	$L > 30$ mm	$20 < L < 30$ mm	$10 < L < 20$ mm	$L < 10$ mm
Diameter (d)	$d < 12.5$ mm	$12.5 < d < 14.5$ mm	$14.5 < d < 17$ mm	$d > 17$ mm

IIA, Internal iliac artery; *IMA*, inferior mesenteric artery.

Proximal aortic neck length is scored as follows: 0, $L \geq 25$ mm; 1, $15 \leq L < 25$ mm; 2, $10 \leq L < 15$ mm; 3, $L < 10$ mm. Proximal aortic neck angle (α or β) is scored as follows: 0, angle ≥ 150°; 1, 150° < angle < 135°; 2, 135° < angle < 120°; 3, angle < 120°. Proximal aortic neck diameter is scored as follows: 0, $d < 24$ mm; 1, $24 \leq d < 26$ mm; 2, $26 \leq d < 28$ mm; 3, $d > 28$ mm. Calcification or thrombus is scored as follows: 0, calcification < 25% of circumference, atheroma, or thrombus (>2 mm thick) < 25% of circumference; 1, calcification 25% to 50% of circumference, atheroma, or thrombus (>2 mm thick) 25% to 50% of circumference; 2, calcification > 50% of circumference, atheroma, or thrombus (>2 mm thick) > 50% of circumference. Scoring the distal aortic neck, as it pertains to implantation of aortic tube endografts, can be performed using a similar grading scheme. However, angulation of the distal neck (θ) is defined as the angle between the flow axis of the distal infrarenal neck and the common iliac artery.

Aneurysm dimensions and branch vessels

Aneurysm morphology may influence endograft delivery, deployment, and embolization risk, as well as long-term device performance, including the potential for achieving complete aneurysm exclusion. Admittedly, the data pertaining to patency of aortic branch vessels, including lumbar arteries and the inferior mesenteric artery (IMA), and risk of endoleak are limited.

Definitions and scoring relevant to an aortic aneurysm. The *aortic tortuosity* index (T) is defined as $T = L_1/L_2$ where L_1 is the distance along the central lumen line between the lowest renal artery and the aortic bifurcation (without deviation into saccular areas or blebs) and L_2 is the straight-line distance from the lowest renal artery to the aortic bifurcation (Fig 1, *B*). The aortic angle (Φ) is the most acute angle in the pathway between the lowest renal artery and the aortic bifurcation. Ideally, both the aortic angle and tortuosity index are measured from spatially-correct three-dimensional data. They are scored as follows: 0, $T \leq 1.05$ or an aortic angle (Φ) between 160° and 180°; 1, $1.05 < T \leq 1.15$ or Φ between 140° and 159°; 2, $1.15 < T \leq 1.2$ or Φ between 120° and 139°; 3, $T > 1.2$ or $\Phi <$ 120°. *Thrombus* is scored as follows: 0, no visible thrombus; 1, <25% of the cross-sectional area; 2, 25% to 50% of the cross-sectional area; 3, >50% of the cross-sectional area. A similar grading scheme can be used if common and external iliac artery aneurysms are present (>2 cm) and the magnitude of thrombus is graded for each iliac segment. *Aortic branch vessels* are scored as follows: 0, no lumbar arteries, IMA, or other branches visibly patent; 1, one patent lumbar artery or IMA; 2, at least 2 patent branch vessels (lumbar arteries or IMA), none >4 mm in diameter; 3, any one of the following with at least 2 patent branch vessels—paired lumbar arteries, low-resistance outflow vessel (uncovered accessory renal artery), or IMA >4 mm in diameter.

Iliac artery

Iliac artery morphology is crucial to obtaining delivery device access into the aorta, sealing the aneurysm from systemic intraluminal pressure, and maintaining perfusion to the pelvis and adjacent areas. Categorization and grading are based on several characteristics—calcification, diameter, angulation or tortuosity, and length using a 0 to 3 scale

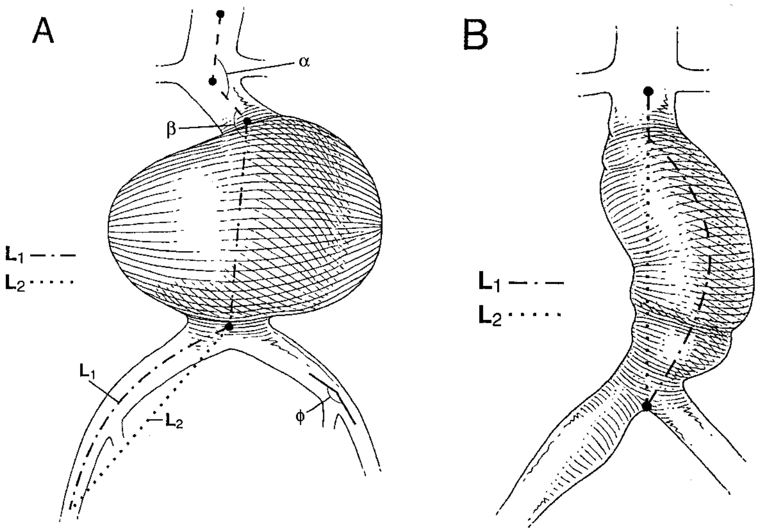

Fig 1. Definitions pertaining to angulation and tortuosity of the aortic neck and iliac arteries (**A**) and body of the aneurysm (**B**).

for each characteristic—and they are graded for each iliac segment (ipsilateral and contralateral to the main device, common, and external), unless otherwise specified.

Definitions relevant to the common and external iliac artery segments. *Calcification* is scored as follows: 0, no calcification; 1, scattered calcifications over 25% or less of the segment length; 2, between 25% and 50% of the segment length; 3, more than 50% of the segment length calcified or circumferential at any level.

Iliac diameter and the presence or absence of stenotic segments will impact device access, attachment site durability, and sealing. For example, iliac aneurysms may affect the durability of the attachment or seal (see sealing zone below), and iliac stenoses may affect delivery device access or endograft patency. Thus, grading is based on a consideration of both a representative diameter (d) and the extent of occlusive disease, as follows: 0, $d \geq 10$ mm with no occlusive disease; 1, $8 \leq d < 10$ mm with no stenosis <7 mm diameter or >3 cm long; 2, $7 \leq d < 8$ mm or any diameter with a focal stenosis <7 mm diameter and <3 cm in length; 3, any one of the following—$d < 7$ mm, stenosis <7 mm in diameter and ≥ 3 cm in length, or more than one focal stenosis <7 mm in diameter.

The *iliac tortuosity* index (τ) is defined as $\tau = L_1/L_2$ where L_1 is the distance along the central lumen line between the common femoral artery and the aortic bifurcation and L_2 is the straight-line distance from the common femoral artery and the aortic bifurcation (Fig 1, *A*). The iliac angle (ϕ) is the most acute angle in the pathway between the common femoral artery and the aortic bifurcation. Ideally, both the iliac angle and iliac tortuosity index are measured from spatially-correct three-dimensional data. They are scored as follows: 0, $\tau \leq 1.25$ or an iliac angle (ϕ) between 160° and 180°; 1, $1.25 < \tau \leq 1.5$ or ϕ between 121° and 159°; 2, $1.5 < \tau \leq 1.6$ or ϕ between 90° and 120°; 3, $\tau > 1.6$ or $\phi < 90°$.

Iliac artery sealing zone length was measured as follows: 0, $L \geq 30$ mm; 1, $20 \leq L < 30$ mm; 2, $10 \leq L < 20$ mm; 3, $L < 10$ mm. *Iliac artery sealing zone diameter* was measured as follows: 0, $d \leq 12.5$ mm; 1, $12.5 < d \leq 14.5$ mm; 2, $14.5 < d \leq 17$ mm; 3, $d > 17$ mm.

Definitions relevant to the internal iliac artery and pelvic collaterals. Internal iliac artery patency may affect outcomes related to the preservation of pelvic perfusion, including the development of claudication, colon ischemia, paraparesis, or paraplegia. Therefore, categorization and grading is based on vessel patency and the presence of occlusive disease. Pelvic perfusion should be graded after all maneuvers leading to endograft deployment to account for intentional or inadvertent occlusion of the hypogastric arteries.

Pelvic perfusion is scored as follows: 0, patent hypogastric arteries bilaterally, no occlusive disease; 1, unilateral intentional, inadvertent, or chronic hypogastric artery occlusion and no significant occlusive disease in the remaining single patent hypogastric artery; 2, unilateral intentional, inadvertent, or chronic hypogastric artery occlusion plus significant occlusive disease ($>50\%$ stenosis) in the remaining single patent hypogastric artery or one of its major branches; 3, bilateral hypogastric artery occlusion.

Categorization to yield anatomic subscores grading risk for access failure or endograft limb obstruction

For studies investigating the risk of access failure or endograft limb obstruction, the tortuosity, diameter, and degree of calcification along the entire deployment pathway may influence the risk of these periprocedural complications. Thus, a calculated score to stratify the risk of access failure or endograft limb obstruction is proposed that consists of the sum of scores grading the *diameter*, *calcification*, and *tortuosity* of the entire ileofemoral artery pathway. A 30-point maximum scale is generated that can be divided by 10 to yield an anatomic severity score on a 3-point scale.

Anatomic subscores can also be reported separately for ipsilateral and contralateral pathways (15-point scale), so those factors that influence either the main device or the contralateral limb, where applicable, can be evaluated. In this case, scores for either ipsilateral or contralateral pathways can be divided by 5 to yield an access-related anatomic severity score on a 3-point scale.

Categorization to yield an anatomic score grading the risk of embolization

For studies focused on the risk of embolization, the tortuosity, angulation, and extent of intraluminal thrombus along the entire deployment pathway may influence the risk of periprocedural embolization. Thus, a calculated score to stratify the risk of embolization is proposed that consists of the sum of scores grading iliac and aortic tortuosity and thrombus load. As an example, if catheter manipulation is performed along both iliac pathways, in the presence of bilateral common iliac artery aneurysms (>2 cm), grading would be performed using an 18-point maximum scale that includes grades for aortic tortuosity (0-3) and thrombus (0-3), right iliac tortuosity (0-3), and thrombus (0-3), as well as left iliac tortuosity (0-3) and thrombus (0-3). The summed score should be divided by 6 to yield an embolization-related anatomic severity score on a 3-point scale.

Categorization to yield an anatomic score grading the risk of endoleak

For investigations that are directed at characterizing failure of aneurysm exclusion caused by endoleak or endotension, morphologic characteristics of the aortic neck, aneurysm, and iliac arteries may influence this phenomenon. Thus, a calculated score to stratify the risk of failed aneurysm exclusion is proposed that consists of the sum of scores grading the following: (1) aortic neck (12-point maximum); (2) iliac artery sealing zone (6-point maximum per iliac); and (3) aortic branch vessels (3-point maximum). In the case of a bifurcated endograft, as an example, grading of endoleak risk would be performed on a 27-point scale. The summed score should be divided by 9 to yield an endoleak-related anatomic severity score on a 3-point scale.

Categorization to yield an anatomic score grading the risk of a "failed deployment"

Deployment failure can be caused by various factors, such as access failure of the delivery device, proximal endoleak requiring immediate conversion to open repair, vessel injury requiring conversion, or inability to remove the delivery device after successful deployment of the stent-graft itself. Thus, a calculated score to stratify the risk of deployment failure is proposed that consists of the sum of scores grading the following: (1) aortic neck; (2) aortic angulation and tortuosity; and (3) diameter, calcification, and tortuosity of the entire ileofemoral artery pathway.

GLOBAL SCORING SYSTEM FOR ENDOGRAFT REPAIR: COMBINED USE OF COMORBIDITY AND ANATOMIC SEVERITY SCORING SYSTEMS

Total morbidity and mortality during the perioperative period are influenced by both comorbid medical conditions and anatomic factors that influence the risk of failed deployment, embolization, and complications related to pelvic ischemia. Thus, in providing a global scheme for grading risk of major morbidity and mortality, it is recommended that a calculated score be comprised by the weighted addition of the following: (1) medical comorbidity severity score; and (2) anatomic severity scores related to the presumed risk for (a) failure of device deployment, (b) pelvic ischemia, and (c) embolization (Table IV). As described, each of these subscores can be graded using a 0 to 3 scale. In recognition of the dominant roles of medical comorbidity and anatomic factors that affect the risk of failed deployment, quadruple weighting is applied to these scores. The pelvic ischemia score is single. Risk of clinically relevant embolization may increase with the introduction of low-profile percutaneous systems. However, currently the risk of significant embolization appears to be low and is singly weighted. The maximum allowable combined global severity score using this scheme is 30. Thus, scores can be divided by 10 to yield a Global Severity Score on a 3-point scale. It is anticipated that continued experience with endovascular aneurysm repair will help to further refine factor weighting. Nevertheless, in the absence of prospective randomization, risk stratification provides a means, however limited, for rational comparison of disparate study populations.

Table IV. Global scoring system for stratifying the risk of major morbidity and mortality after endograft repair

Risk factor	*Weighting*	*Score*
Combined medical comorbidity	×4	12
Anatomic factors that influence failed deployment	×4	12
Pelvic ischemia	×1	3
Embolization	×1	3
Maximum score*		30

*Divide by 10 to restore 3 point scale.

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