Reporting standards for infrarenal endovascular abdominal aortic aneurysm repair

Samuel S. Ahn, MD, Robert B. Rutherford, MD, K. Wayne Johnston, MD, James May, MD, Frank J. Veith, MD, J. Dennis Baker, MD, Calvin B. Ernst, MD, and Wesley S. Moore, MD, for the Ad Hoc Committee for Standardized Reporting Practices in Vascular Surgery of The Society for Vascular Surgery/International Society for Cardiovascular Surgery

Currently, there is great interest in the experimental technique of endovascular aortic aneurysm repair. The number of reports in the literature has increased in the past 5 years. The ability to interpret future clinical reports and to compare the advantages and disadvantages of the various devices and techniques requires a uniform standard for analyzing and reporting the data. Previous experience with reports on the other endovascular devices (including percutaneous transluminal angioplasty, atherectomy catheters, and lasers) has clearly shown that investigators, left on their own, may report their results in a variety of ways, which make comparison of one report to the other difficult, if not impossible. Consequently, to provide valid comparisons among reported results of endovascular management methods for abdominal aortic aneurysm, disease, the following guidelines are recommended.

PATIENT ASSESSMENT

Clinical classification

In addition to the classification categories recommended in the SVS/ISCVS' Suggested Standards for Reporting on Arterial Aneurysms,[1] patients undergoing endograft repair should be stratified by symptoms and clinical presentation, as follows:

Stage I: Asymptomatic
Stage II: Intact but symptomatic
Stage III: Contained rupture
Stage IV: Free rupture

Patients with dissecting aneurysm should be categorized separately because the complexity and technical challenge of treating this disease are greater.

Hemodynamic assessment

Preoperative resting ankle-brachial indexes (ABI) are needed as a baseline to help determine the severity of any thrombotic or embolic complications after synergy. In diabetic patients with noncompressible arteries, alternative tests should include toe pressures, pulse volume recording, or Doppler waveform, as recommended by the Ad Hoc Subcommittee on Reporting Standards.[2,3]

Risk factors

Patient demographic and risk factor variables should be reported, including tobacco use, hypertension, diabetes mellitus, hyperlipidemia, chronic obstructive pulmonary disease, cardiac disease, carotid occlusive disease, renal insufficiency, and presence of other aneurysms using the criteria in the SVS/ISCVS standards and guidelines.[1-3] Anesthetic risk should be reported according to the American Society of Anesthetist Risk Classification (ASA I-IV).

Anatomic characteristics

The technical difficulty of endovascular repair is greatly influenced by the morphologic features of the aneurysm and its adjacent vessels. Accordingly, the following characteristics should be individually recorded and reported for each aneurysm, and the following grading scheme for these characteristics

Reprint requests: Samuel S. Ahn, MD, 100 UCLA Medical Plaza, Suite 510, Los Angeles, CA 90024.
J Vasc Surg 1997;25:405-10.

0741-5214/97/$5.00 + 0 24/1/79023

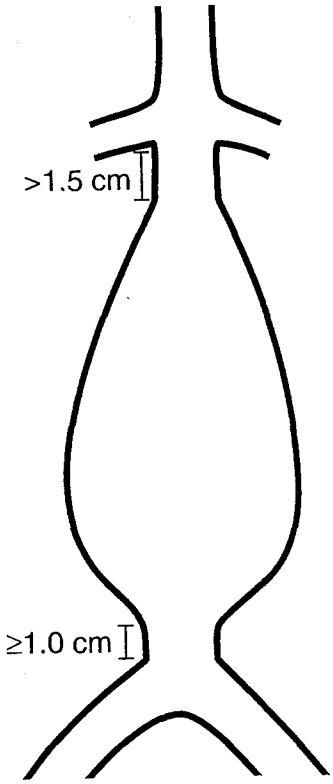

Fig. 1. Grade I extent of aneurysm involvement: length of proximal neck 1.5 cm or greater and distal neck 1.0 cm or greater.

should be used in stratifying the aneurysms for analysis.

1. Greatest mural diameter of abdominal aortic aneurysm (CT scan measurement):
   Small (S): Less than 5 cm.
   Medium (M): 5 to 6.5 cm.
   Large (L): Greater than 6.5 cm.
2. Extent of aneurysm involvement:
   Grade I: Length of proximal neck ≥1.5 cm and distal neck ≥1.0 cm (Fig. 1).
   Grade II: Length of proximal neck ≥1.5 cm, but distal neck <1.0 cm without obvious iliac aneurysms (Fig. 2, *A*), or aneurysm extends into or is associated with iliac aneurysms (Fig. 2, *B*).
   Grade III: Length of proximal neck <1.5 cm and distal neck ≥1.0 cm (Fig. 3).
   Grade IV: Length of proximal neck <1.5 cm *and* distal neck <1.0 cm or iliac involvement as in Grade II (Fig. 4).
3. Tortuosity of aorta—because of multiple angles, the worst (greatest) angle should be used in grading:
   Grade I: 180° to 150° (180° = straight aorta without any tortuosity) (Fig. 5).
   Grade II: 150° to 120° (Fig. 6).
   Grade III: Less than 120° (Fig. 7).
4. Anatomy of the iliac arteries:
   The absence or presence of iliac artery occlusive disease, which requires intervention (i.e., balloon

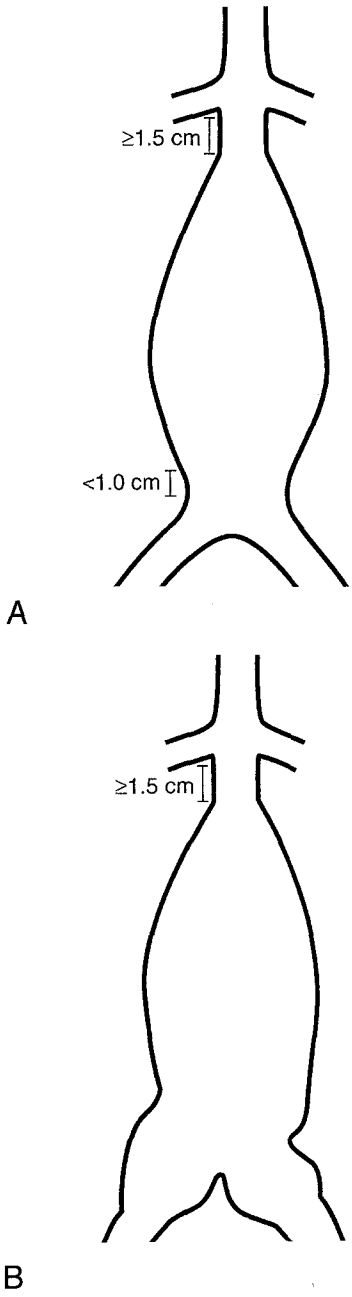

Fig. 2. A, Grade II extent of aneurysm involvement: length of proximal neck 1.5 cm or greater, but distal neck less than 1.0 cm without obvious iliac aneurysms, or **B,** aneurysm extends into or is associated with iliac aneurysms.

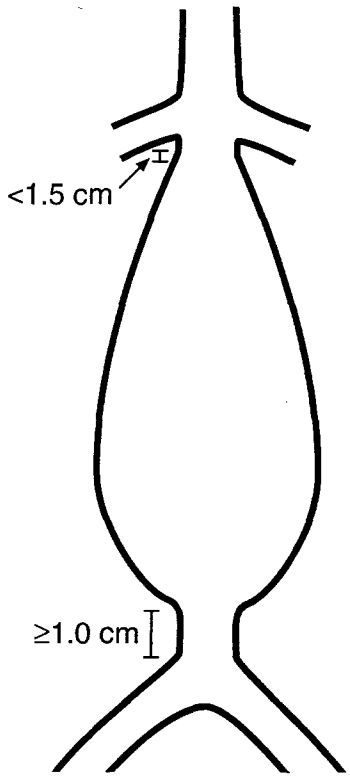

Fig. 3. Grade III extent of aneurysm involvement: length of proximal neck less than 1.5 cm and distal neck 1.0 cm or greater.

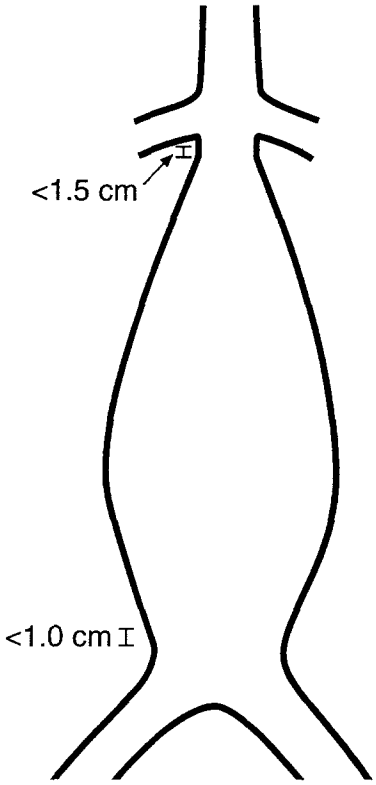

Fig. 4. Grade IV extent of aneurysm involvement: length of proximal neck less than 1.5 cm *and* distal neck less than 1.0 cm or iliac involvement as in grade II.

angioplasty) for any reason, including the introduction of the endograft carrier system, should be noted and designated as A (absent) or B (present). The least diameter of the iliac arteries should be recorded as suggested by Veith et al.[4] Similarly, the absence or presence of iliac tortuosity severe enough to require intervention (i.e., mobilization to straighten out a tortuous iliac artery or transretroperitoneal temporary attachment of a prosthetic graft to the iliac artery) should be designated as N (nontortuous) or T (tortuous). The actual number or percentage of these patients should be reported.

An asymptomatic 6.0 cm, "straight" aortic aneurysm, with good proximal and distal necks and without stenotic or tortuous iliac arteries, would be categorized as Clinical Stage I, Size M, Neck Grade I, Angle Grade I, Iliac A,N. These anatomical characteristics should be based on a combination or aortographic and computed tomographic (CT) or magnetic resonance (MR) imaging scans, preferentially with three-dimensional reconstruction when available. Both aortographic and CT/MR imaging methods are required to allow precise measurement of the characteristics listed above.

DEVICE-RELATED FACTORS

The devices and grafts should be classified according to their configuration (straight vs bifurcated); the material used (Dacron vs PTFE vs polyurethane, etc.); the type of fixation system and manufacturer of the device[4]; and the diameter of the proximal and distal fixation sites.

PHARMACOLOGIC THERAPY

Adjunctive pharmacologic therapy such as aspirin, heparin, sodium, coumadin, vasodilators, and/or thrombolytic agents, along with their dosage and duration of treatment, should be described. The type and volume of contrast agent used during the procedure should be documented.

MISCELLANEOUS FACTORS

Type of anesthesia (general, spinal, local, etc.), duration of surgery (skin open to skin closure), estimated blood loss, and transfusion (within 24 hr)

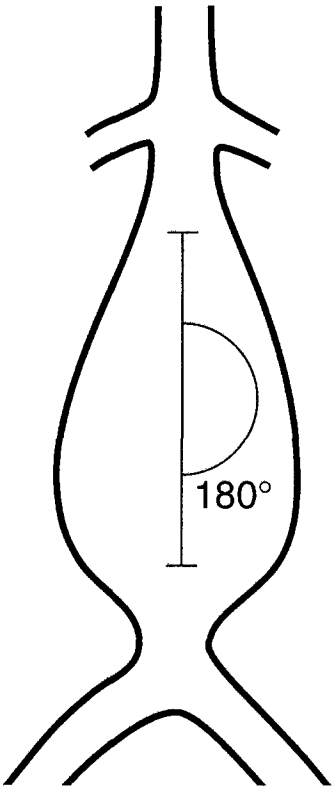

Fig. 5. Grade I tortuosity of aorta: 180° to 150°.

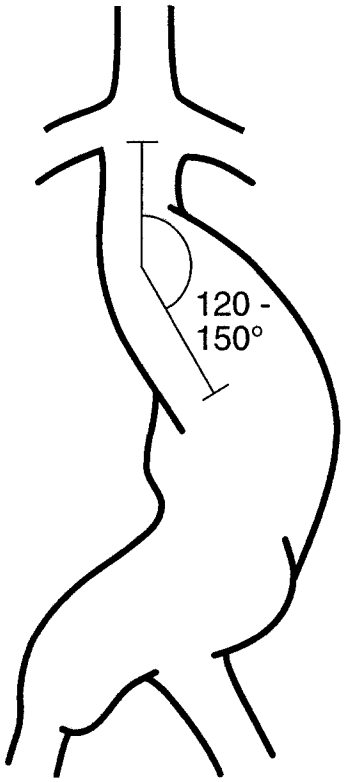

Fig. 6. Grade II tortuosity of aorta: 150° to 120°.

should be reported. Furthermore, the point of entry or approach (i.e., femoral vs iliac vs brachiocephalic artery cutdown vs percutaneous route) should be recorded and reported.

CRITERIA FOR SUCCESS

Technical success

Treatment outcome must be based on intent-to-treat and includes all patients who consent to undergo the procedure. Technical success is defined as the proper placement of the graft by using endovascular techniques. This involves the following:

1. Successful access to the arterial system using a remote site, i.e., the femoral, external iliac, common iliac, or brachiocephalic arteries with or without use of a temporary or permanent prosthetic conduit to access these arteries.
2. Successful deployment of the endoluminal graft with secure proximal and distal fixation of the attachment devices without persistent perigraft endoleakage. Small, transient (<48 hr) perigraft extravasation of the contrast medium through the graft interstices or around the graft (an endoleak) should be recorded and reported, but is not considered a leak or a technical failure. However, a persistent leak (≥48 hr) of blood through the graft or an endoleak around the proximal or distal ends of the graft constitutes a failure, even if it is not treated.
3. Patent endoluminal graft without significant twist, kinks, or obstruction (<20%) by intraoperative angiogram diameter measurements.

Technical success must be documented by operative aortographic scan and follow-up CT scan, color Duplex scan, or angiogram. Intravascular ultrasonography may be a helpful adjunct but is not required. The inability to gain aortic access through a remote site, to properly deploy the graft, to properly secure the graft without leak, or need for conversion to standard aortic reconstruction for any reason should be considered a technical failure.[4]

The technical success without death or need for standard aortic reconstruction must be maintained for 30 days for the procedure to be considered successful. Reports should also include the range and average number of days on a ventilator, in an intensive care unit, and in the hospital. Furthermore, reporting the average hospital charges and cost per

patient is recommended. Finally, if available, the number of days to return to the preprocedure daily activity level and patient satisfaction should be reported. If so, the precise definitions and techniques for determining these factors must be explained.

Clinical success

Clinical success is defined similarly to technical success except for the presence or absence of perigraft endoleak. This exception is important because small endoleaks may seal spontaneously without treatment, and the patients subsequently have done well. Thus clinical success (although a technical failure) can still be claimed, even if the patient has a persistent endoleak that seals spontaneously within 6 months and does not develop aneurysmal expansion or rupture. Graft endoleaks that persist longer than 6 months or aneurysms that expand should be considered clinical failures because late rupture has been reported under such circumstances. *Any* subsequent intervention directed at the above events also constitute clinical failure.

Continuing success

Continuing success is defined as maintenance of the technical *and* clinical success with no evidence of graft thrombosis, migration, infection, or dilatation greater than 20% by diameter; aneurysmal degeneration proximal or distal to the graft; fixation device failure; aneurysmal expansion by 0.5 cm or greater; or requirement for open conversion. Any occurrence of such adverse outcomes constitutes failure of the procedure. Any other reasons for graft replacement using open techniques should also be considered a failure. Any late graft complications that are successfully treated with another endovascular or other less-invasive procedure (i.e., another graft or stent inserted for stenosis, dilatation, persistent leaks, or to control migration) that does not replace the original graft can be counted as a secondary success.

Duration of successful outcome is considered short-term if the above requirements are met for 6 months, midterm if maintained for 2 years, and long-term after 5 years.

Life tables or Kaplan-Meier curves should be calculated to record data on maintenance of technical and clinical success. These overall results should also be dissected to present separately survival, rupture-free survival, stability of aneurysm size, and graft patency. Late results require at least 5 year follow-up. Results of 2- to 5-year follow-up are considered midterm or intermediate. Follow-up less than 6 months should be reported as preliminary short-term data.

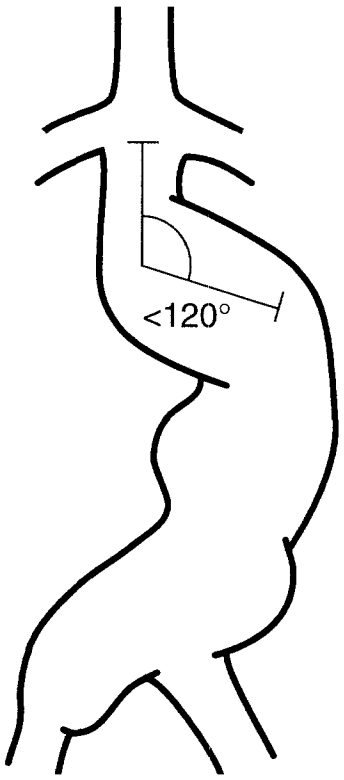

Fig. 7. Grade III tortuosity of aorta: less than 120°.

COMPLICATIONS

Local vascular complications

Bleeding is considered a complication if surgical treatment or transfusion of more than 2 units of blood are required. The range and average volumes of estimated blood loss and transfusion requirements should be recorded. A hematoma or pseudoaneurysm at any access site should be reported if further treatment (medical or surgical) is required or if hospital discharge is delayed. An infection is considered to be present if the access site or the endoluminal graft are involved. Thromboembolic complications include distal emboli, graft thrombosis, or access site thrombosis. Intestinal ischemia should be listed as a separate complication. If a perigraft endoleak is treated conservatively, comprehensive follow-up evaluation is required. Any aneurysmal rupture or death must be reported.[4] Late migration of the graft or attachment device failure or defects must be reported.

Remote systemic complications

Other procedural complications that must be reported include myocardial infarction, cardiac failure, renal failure, respiratory failure, pneumonia, atelectasis, hepatic failure, urinary tract infection, coagulopa-

thies, hypercoagulable states, and fever.[4] Renal failure requires particular attention, because the most common cause is a large contrast load, which may reflect technical problems. These must be reported and defined as recommended.[1,2] Any death within 30 days regardless of cause is considered a procedure-related death.

FOLLOW-UP DATA

A follow-up protocol should include clinical status and physical examination, ABI, *and* a contrast-enhanced CT scan at least every 6 months. Aneurysm size and lack of contrast enhancement (leak) outside the endograft must be documented. A duplex scan or aortogram is recommended but not required unless clinically indicated to clarify abnormalities found by the required studies,[4] that is, to evaluate endoleaks, kinks, or narrowing of endograft. Plain x-ray films should be obtained to detect defects in the fixation devices.

CONCLUDING REMARKS

These recommendations are based on current knowledge of the new technology. Because this field is still evolving, it is quite likely that modifications of these reporting standards will be required. Nevertheless, these guidelines provide uniformity in reporting so that the various devices can be analyzed and compared.

We thank Blessie Concepcion for her assistance in the preparation of this manuscript.

REFERENCES

1. Johnston KW, Rutherford RB, Tilson MD, Shah DM, Hollier L, Stanley JC. Suggested standards for reporting on arterial aneurysms. J Vasc Surg 1991;13:452-8.
2. Rutherford RB, Flanigan DP, Gupta SK, Johnston KW, Karmody A, Whittemore AD, et al. Suggested standards for reports dealing with lower extremity ischemia. J Vasc Surg 1986; 4:80-94.
3. Ahn SS, Rutherford RB, Becker GJ, Comerota AJ, Johnston KW, McClean GK, et al. Reporting standards for lower extremity arterial endovascular procedures. J Vasc Surg 1993;17: 1103-7.
4. Veith FJ, Abbott WM, Yao JST, Goldstone J, White RA, Abel D, et al. Guidelines for development and use of transluminally placed endovascular prosthetic grafts in the arterial system. J Vasc Surg 1995;21:670-85.

Submitted Aug. 30, 1996; accepted Nov. 1, 1996.