Predicting iliac limb occlusions after bifurcated aortic stent grafting: Anatomic and device-related causes

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Objective: **Graft limb occlusion may complicate endovascular abdominal aortic aneurysm repair. The precise etiologic factors that contribute to the development of these graft limb thromboses have not been defined. We evaluated our experience with bifurcated aortic endografts to determine factors that may predict subsequent limb thrombosis. The management of the thrombosed limbs and the results after treatment were also investigated.**

Methods: **During a 4-year period, 351 patients with aortic aneurysms underwent treatment with bifurcated endografts (702 graft limbs at risk). These 351 bifurcated devices included AneuRx (Medtronic, Minneapolis, Minn; n = 35), Ancure (Guidant, Menlo Park, Calif; n = 8), Gore (W.L. Gore & Associates, Sunnyvale, Calif; n = 25), Talent (World Medical, Sunrise, Fla; n = 255), Teramed (Teramed, Minneapolis, Minn; n = 10), and Vanguard (Boston Scientific Vascular, Natick, Mass; n = 18). Details regarding the type of device, mechanism of deployment, and aortoiliac artery anatomy were collected prospectively and analyzed. Graft limbs were analyzed for diameter, use of additional endograft iliac extensions, deployment in the external iliac artery, and endograft to vessel oversizing. Follow-up included physical examination, duplex ultrasonography, and spiral computed tomographic scans at 1 month, 6 months, and 12 months and annually thereafter. The follow-up period ranged from 2 to 54 months, with a mean follow-up period of 20 months.**

Results: **Twenty-six of 702 limbs (3.7%) had an occlusion develop. The risk of limb thrombosis was associated with a smaller limb diameter. Mean graft limb diameter was 14 mm in the occluded population, and patent limbs had a mean diameter of 16 mm. Thrombosis occurred in 16 of 291 limbs (5.5%) that were 14 mm or less and in 10 of 411 limbs (2.4%) that were greater than 14 mm (*P* = .03). Extension of a graft to the external iliac artery was performed in 96 of the 702 limbs. Eight of these 96 limbs (8.3%) had thrombosis develop as compared with 18 of 606 (3.0%) that extended to the common iliac artery (*P* = .01). No significant association was present between limb thrombosis and the contralateral or ipsilateral side of a device, the configuration of the iliac graft limb end (closed web, open web, or bare spring), or the degree of iliac graft limb oversizing. AneuRx, Ancure, Vanguard, and Talent grafts each sustained limb occlusions, with no occlusions seen among the Gore and Teramed devices. No significant increased risk of graft limb thrombosis was observed in unsupported grafts (1/16; 6.3%) versus supported grafts (25/686; 3.6%; *P* = not significant). Thromboses occurred between 1 day and 23 months after surgery. Thirteen of the 26 thromboses (50%) occurred within 30 days of surgery. Presenting symptoms were mild to moderate claudication in eight patients (30.8%), severe claudication in 16 patient (61.5%), and paresthesia and rest pain in two patients (7.7%). Eighteen of 26 patients (69.2%) eventually needed intervention to reestablish flow to the occluded limb, including thrombolysis and stenting in two patients (7.7%), axillary femoral bypass in one patient (3.8%), femoral-femoral bypass in 13 patients (50.0%), and axillary-bifemoral bypass in two patients (7.7%). All patients with mild to moderate symptoms under observation had improvement in symptoms with no further interventions necessary. All revascularizations were successful in relieving symptoms.**

Conclusion: **Graft limb occlusion is a recognized complication of endovascular treatment of abdominal aortic aneurysms that may be associated with smaller graft limb diameter and extension to the external iliac artery. Occlusions usually necessitate additional intervention for resolution of ischemic symptoms. The use of small diameter grafts should be avoided when possible to reduce the risk of graft limb occlusions. (J Vasc Surg 2002;36:679-84.)**

Aortic endograft limb thrombosis is a known complication after endovascular repair of infrarenal abdominal aortic aneurysms.[1-9] After limb thrombosis, symptoms may necessitate additional interventions, including endovascular and direct surgical revascularization.[10-12] These interventions have associated morbidity and often necessitate rehospitalization. This study analyzed the factors associated with bifurcated endovascular graft limb thrombosis and assessed the treatment and outcome during a 4-year period.

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PATIENTS AND METHODS

From July 1997 to December 2001, 351 patients with infrarenal aortic aneurysms underwent treatment with bifurcated endografts at the Mount Sinai Medical Center, yielding a population of 702 limbs at risk for thrombosis. All data regarding each procedure were entered prospectively into a vascular registry. All procedures were per-

Table I. Factors investigated for association with graft limb thrombosis

Limb status (no.)	*Limb diameter (mean; mm)*	*Extension to external iliac*	*Additional extension*	*Device oversizing (mean; mm)*
Patent (676)	15.8 ± 3.4	13.1% (88/676)	25.4% (172/676)	1.49 ± 0.9
Occluded (26)	14.3 ± 2.2	30.8% (8/26)	19.2% (5/26)	1.42 ± 0.8
P value	.02	.01	.5	.07

Table II. Rate of limb occlusion among devices

Device	*Total limbs (n = 702)*	*Occluded limbs (n = 26)*
AneuRx	70	1 (1.4%)
Ancure	16	1 (6.3%)
Gore	50	0
Talent	510	20 (3.9%)
Teramed	20	0
Vanguard	36	4 (11.1%)

Table III. Rate of limb occlusion in supported versus unsupported devices

Device limbs	*Total limbs*	*Occluded limbs*
Supported	686	25 (3.6%)
Unsupported	16	1 (6.3%)

formed with protocol approved by the institutional review board. Specific factors analyzed were graft limb diameter, iliac artery diameter, graft to vessel oversizing, deployment to the external iliac artery, identification of contralateral or ipsilateral limb, device type, and support. Devices used were AneuRx (Medtronic, Minneapolis, Minn; n = 35), Ancure (Guidant, Menlo Park, Calif; n = 8), Excluder (W.L. Gore & Associates, Sunnyvale, Calif; n = 25), Talent (World Medical, Sunrise, Fla; n = 255), Ariba (Teramed, Minneapolis, Minn; n = 10), and Vanguard (Boston Scientific Vascular, Natick, Mass; n = 18).

The follow-up period ranged from 2 to 54 months (mean, 20 ± 9 months). History and physical examination, radiograph, duplex scan, and 3-mm slice computed tomographic scan with intravenous contrast were performed at 1 month, 3 months, 6 months, and 12 months after surgery and annually thereafter. Limb occlusions were identified at office visit follow-up and at emergency department visits when symptoms were acute. Computed tomographic scan confirmed graft limb thrombosis in all 26 cases, duplex ultrasound scan in six cases, and angiography in two cases. Statistical analysis was performed with regression analysis.

RESULTS

Thrombosis occurred in 26 of the 702 limbs at risk (3.7%). Investigation of factors that potentially predisposed to limb thrombosis identified a significant association between the mean limb diameter and the occurrence of a limb thrombosis (Table I). Although the endografts limbs used during the study period included diameters that ranged from 8 to 24 mm, the population of occluded limbs had a significantly smaller mean diameter. Occluded limbs ranged in size from 12 to 20 mm. Among the total population of limbs, 41.5% had diameters of 14 mm or less and 91.7% had limb diameters of 16 mm or less. With a threshold limb diameter of 14 mm or less, thrombosis was significantly more common in limbs 14 mm or less (16/291 limbs; 5.5%) than in limbs greater than 14 mm (10/411 limbs; 2.4%; $P = .03$). Included in the investigation was the degree of graft oversizing of the vessel. No significant difference was seen in degree of oversizing between the population of occluded limbs and the patent limbs (mean, 1.42 ± 0.8 mm oversizing versus 1.49 ± 0.9 mm oversizing; P = not significant). Six of 144 limbs without oversizing (4.5%) resulted in thrombosis, and 20 of 558 oversized limbs (3.6%) resulted in thrombosis, confirming no association with limited oversizing.

Graft limbs occluded more frequently when extended to the external iliac artery. Extension of a graft to the external iliac artery was performed in 96 of the 702 limbs. Eight of these 96 limbs (8.3%) had thrombosis develop as compared with 18 of 606 (2.9%) that extended to the common iliac artery ($P = .01$). In modular grafts, limb occlusion was not increased in the contralateral iliac modular limb as compared with the ipsilateral limb that originated from the main body of the device. In addition, the use of additional iliac extensions had no association with limb thrombosis. Rates of limb occlusion were identified for each design (Table II). Investigation into the type of device failed to reveal an association between the unsupported devices and the development of limb occlusion. Limb thrombosis was observed in one of 16 unsupported grafts (6.3%) versus 25 of 686 supported grafts (3.6%; P = not significant; Table III). Although a minority of the patient population had endoluminal or extraluminal accessory conduits to allow endograft insertion, no limb occlusions occurred within this population of patients.

Thirteen of the 26 limb occlusions (50%) were identified within 30 days after the aneurysm repair (Table IV). Nearly all 24 of 26 (92.3%) occurred within the first year of follow-up. The mean time to occlusion was 5.2 ± 6.5 months, with a range from 1 day to 23 months. Patients with occluded graft limbs had symptoms that ranged from mild claudication to rest pain with paresthesia. Presenting symptoms were mild to moderate claudication in eight patients (30.8%), severe claudication in 16 patients (61.5%), and paresthesia and rest pain in two patients (7.7%). No loss of motor function was found in any patients. The patients with more severe symptoms (18/26) were seen at the emergency department. Physical examination identified the loss of the femoral pulse in all the patients with thromboses.

The severity of the symptoms determined the need and timing of intervention. Although nearly a third of the patients were observed for minor symptoms, 69.2% of patients needed a subsequent procedure to reestablish flow to the affected lower extremity. In the eight patients with limb thrombosis and extension of the graft to the external iliac artery, all eight (100%) had symptoms develop that necessitated intervention, and only 10 of the 18 limbs (55.6%) with distal implantation in the common iliac artery that had thromboses develop needed intervention ($P = .03$). Interventions included thrombolysis and stenting in two patients (7.7%), axillary femoral bypass in one patient (3.8%), femoral-femoral bypass in 13 patients (50%), and axillary-bifemoral bypass in two patients (7.7%; Table V). After intervention, all patients had resolution of symptoms with no permanent sequelae.

Table IV. Interval to occlusion after infrarenal aortic endografting

Occluded limbs	*Time interval to occlusion (mo)*
13 (50%)	≤1
11 (41.7%)	2-12
2 (8.3%)	13-24

Table V. Management of aortic endograft limb occlusion

Occluded limbs	*Treatment*
2 (7.7%)	Thrombolysis and stent
1 (3.8%)	Axillary-femoral bypass
13 (50%)	Femoral-femoral bypass
2 (7.7%)	Axillary-bifemoral bypass
8 (30.8%)	Observation

DISCUSSION

Endograft limb thrombosis after endovascular repair of infrarenal abdominal aortic aneurysm is a recognized complication.[1-9] Factors that have been proposed to potentially predispose to limb thrombosis have included areas of stenosis, such as the aortic bifurcation and occlusive or tortuous iliac arteries,[4,7,13] unsupported endograft devices,[1] irregularity of the endograft lumen from device overlap,[14] stent graft material, and changes in forces, such as extrinsic compression from thrombus and changes in radial force from increasing luminal blood flow.[15,16]

A recognized factor in the risk of graft thromboses is arterial outflow. A limitation in our investigation was the absence of a quantification of arterial outflow in the form of pulse volume recording/arterial brachial index. Although all patients underwent pulse examination before and after surgery, pulse volume recordings were performed only as indicated by protocol by device or with concern for change in pulse examination.

We identified a tendency for endograft limb thrombosis when the limb diameter was small and extended to the external iliac artery. We believe this was likely from the transition that occurred after the bifurcation of the common iliac artery. The path of the vessel was tortuous in the transition from the pelvis toward the groin. Deployment of the device in this location therefore not only resulted in the diminution in size but also an angulation and potential kink in the graft. We can speculate that extension of the endograft limb to the external iliac artery will sacrifice hypogastric artery outflow and prove detrimental to graft limb patency.

One would not expect a diameter of 14 mm to be problematic in terms of limb thrombosis. More likely is that underlying arterial disease is the responsible element and the impact of occlusive disease or tortuosity may be more hemodynamically restrictive to flow. Arterial disease may result in graft limb diameters that are significantly more narrowed when compared with device limbs before insertion. With the exclusion of aneurysmal arteries, which were bridged and not used as fixation sites, the arterial mean diameters in this population were 14 mm for common iliac arteries and 11 mm for external iliac arteries. These measurements were taken from preoperative angiograms and computed tomographic scans that may have limited identification of more stenotic segments. Intravascular ultrasound scan would probably be more beneficial in identification of flow restricting lesions and thus arteries at increased risk for thrombosis.

Although our data fail to reveal any significant association between unsupported devices and limb thrombosis, evidence does exist that lack of device support predisposes to angulation and kinking with resulting stenosis and thrombosis of the graft.[1] Baum and colleagues[1] carried out an investigation of rates of limb kinking in supported and unsupported aortic stent grafts. They identified kinking in 18 of 149 limbs (12%). Limb kinking was significantly more likely in the unsupported groups as opposed to the supported groups. They identified a 5% rate of kinking necessitating intervention in the supported endografts and a rate of 44% in the unsupported grafts. Likewise, the rate of thrombosis was more evident in the unsupported group. Interestingly, not all grafts are supported in a similar fashion. In the Talent device, limb support in the form of a longitudinal bar may restrict kinking if the bar lies on the greater curvature of a bending limb; however, angulation of the same degree with the support bar on the lesser curvature may result in a kink (Fig 1). The devices used in our study were predominantly of the supported structures, with only the Ancure endograft being of the unsupported variety. We did not find the unsupported graft more likely to result in thromboses; however, because Ancure accounted for only 16 of the 702 limbs in the study, a more significant association may be revealed when a larger proportion of the data is available from the unsupported variety of grafts.

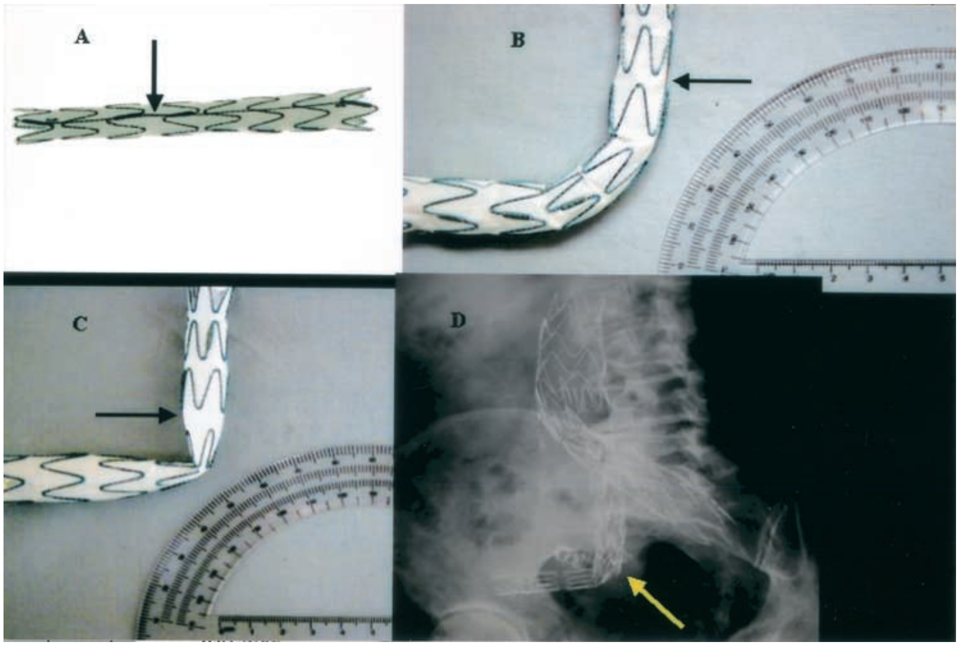

Fig 1. Endograft limb from bifurcated aortic modular graft. **A,** Limb with *arrow* indicates single longitudinal support bar. **B,** Angled endograft with support bar is shown with *arrow* on greater curve. **C,** Angled endograft with support bar on lesser curvature *(arrow)* resulted in endograft kinking. **D,** Abdominal radiograph is shown with kink *(arrow)* in endograft that extended to external iliac artery. Coils are present from preoperative embolization of internal iliac.

When an endograft limb diameter exceeds the native vessel diameter, a degree of graft infolding may be found, which has been identified as a potential site of decreased flow.[2] Despite balloon dilatation for adequate seal, these infoldings, which are more pronounced in the smaller caliber iliac arteries, often persist. Although our study did not identify a difference in the degree of oversizing as a potential risk factor, we did not investigate the degree of oversizing with respect to vessel diameter.

After stent deployment, our intraoperative completion studies consisted of angiography. Although we used angiography in this patient population, we did not use intravascular ultrasound scan. Identification of narrowed areas allows management with balloon dilatation and stenting (Fig 2). In addition, the degree of narrowing could be evaluated with determination of pressure gradients, which was not used in these patients. These attempts at identifying critical stenosis allow one to correct the abnormality at the time of surgery rather than after surgery. Unrecognized stenosis may account for what appears to be success, only to have the thrombosed limb identified in the early postoperative period. With intravascular ultrasound scan, Amesur et al[2] reported a greater ability to identify narrowed limbs immediately after graft placement and treat the unsupported limbs with additional stenting. Although with initial use of angiography alone the rate of limb occlusion was 17%, the institution of intravascular ultrasound scan has improved their detection of stenosis and resulted in no further limb thrombosis at a mean follow-up of 14 months.[2]

Limb thrombosis occurred within 30 days in half of the occlusions. This is likely because of technical factors present at the time of the procedure. Technical and judgement errors responsible for the early postoperative limb occlusions probably relate to tortuous or narrowed iliac arteries. Most patients with limb occlusions did not undergo thrombolysis with subsequent angiography to help identify potential sources of occlusion. In a patient who underwent thrombolysis, a narrowed portion of the graft limb was identified in a calcified occlusive segment of the common iliac artery. Patients with limb occlusions were more often treated without clear identification of the likely source and therefore underwent extraanatomic bypass. The choice of extraanatomic bypass was made on the basis of concern of introducing thrombus into the hypogastric circulation and inability to clearly discern the source of occlusion. Although any concern for femoral arteriotomy closure site narrowing was managed with patch angioplasty, we did not identify any correlation with the closure technique and limb thrombosis. The delayed cases may be from the possible morphologic changes that occur in the aortoiliac anatomy after aneurysm exclusion. Successful exclusion results in aneurysm volume decrease as evidenced by changes in diameter, length, and angulation.[17] In their study, as regression of the AAA occurred, limb length varied from −8 mm to +10 mm, with no consistent pattern for the change. Buckling and angulation can result from these length changes. Studies by Umscheid and Stelter[18] and Harris et al[19] that investigated device conformational changes after aneurysm repair showed patients with late

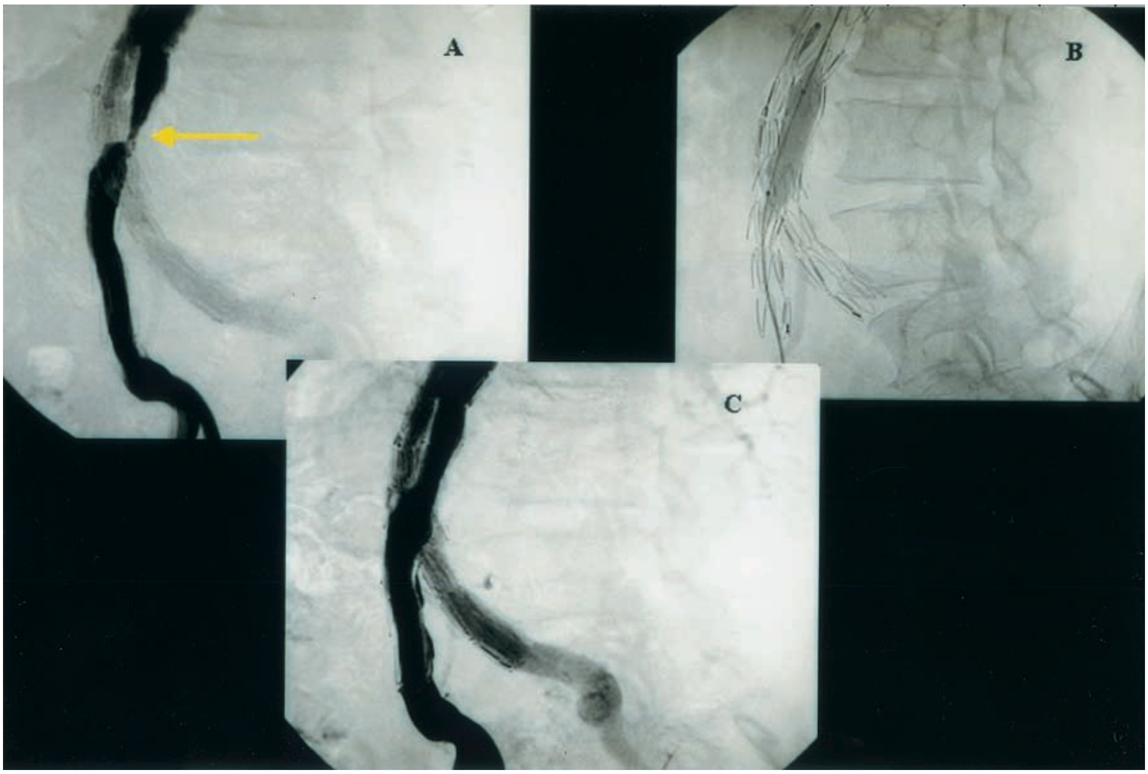

Fig 2. Angiogram after placement of bifurcated aortic endograft. **A,** Area of narrowing *(arrow)* in endograft limb. **B,** Balloon angioplasty of narrowed segment of endograft. **C,** Completion angiogram after dilatation.

complications, including graft limb thrombosis, all with distorted endografts. Comparison of postoperative angiograms after endovascular aneurysm repair revealed endograft buckling in 69% of patients and acutely angled or kinked endografts in 38%.[19] Stent migration, separation, and acute angulation are believed to be predisposing factors. Although early follow-up has shown unsupported grafts are more likely to kink and thrombose,[1] the consequence that long-term morphologic changes in the aneurysm will have on the more rigid supported[19] grafts needs to be further investigated. The need for reintervention is a concern in the follow-up care of patients with aneurysms treated with endovascular repair. In data from the Eurostar registry, the need for reintervention for all indications is estimated at an annual rate of 10%. In their review, limb thrombosis was the most common indication for extraanatomic revascularization,[10] a procedure that entails added morbidity, hospitalization, and cost.

In our population of thrombosed limbs, a third of the patients underwent management with observation for symptoms of mild claudication. The loss of collateral flow from the hypogastric artery, from interruption after placement of the endograft to the external iliac artery, resulted in more progressive symptoms of ischemia when thromboses occurred.

In our series, only two thrombosed limb were managed with endovascular means. The decision to manage the thrombosis with extraanatomic revascularization was because of concerns that thrombectomy may have dislodged the endograft. After thrombolysis and identification of a narrowed graft limb, the placement of a stent within stent reinforced endografts may produce frictional forces that over time could result in fabric failure with subsequent endoleak.[20]

CONCLUSION

Infrarenal aortic aneurysm endografting that uses small aortic graft limb diameter and extension to the external iliac artery predisposes to graft limb thrombosis. Most of these patients will have symptoms that necessitate repeat intervention. Successful intervention, including extraanatomic bypass thrombolysis, angioplasty, and stenting, is successful in reestablishing arterial perfusion and relieving ischemic symptoms without permanent sequelae.

REFERENCES

1. Baum RA, Shetty SK, Carpenter JP, Soulen MC, Velazquez OC, Shlansky-Goldberg RD, et al. Limb kinking in supported and unsupported abdominal aortic stent-grafts. J Vasc Interv Radiol 2000;11: 1165-71.
2. Amesur NB, Zajko AB, Orons PD, Makaroun MS. Endovascular treatment of iliac limb stenoses or occlusions in 31 patients treated with the ancure endograft. J Vasc Interv Radiol 2000;11:421-8.
3. Ohki T, Veith FJ, Shaw P, Lipsitz E, Suggs WD, Wain RA, et al. Increasing incidence of midterm and long-term complications after

endovascular graft repair of abdominal aortic aneurysms: a note of caution based on a 9-year experience. Ann Surg 2001;234:323-45.
4. Carpenter JP, Neschis DG, Fairman RM, Barker CF, Golden MA, Velazquez OC, et al. Failure of endovascular abdominal aortic aneurysm graft limbs. J Vasc Surg 2001;33:296-303.
5. Tillich M, Hausegger KA, Tiesenhausen K, Tauss J, Groell R, Szolar DH, et al. Helical CT angiography of stent-grafts in abdominal aortic aneurysms: morphologic changes and complications. Radiographics 1999;19:1573-83.
6. Mita T, Arita T, Matsunaga N, Furukawa M, Zempo N, Esato K, et al. Complications of endovascular repair for thoracic and abdominal aortic aneurysm: an imaging spectrum. Radiographics 2000;20:1263-78.
7. Chuter TA, Wendt G, Hopkinson BR, Scott RA, Risberg B, Keiffer E, et al. Bifurcated stent-graft for abdominal aortic aneurysm. Cardiovasc Surg 1997;5:388-92.
8. Chuter TA, Gordon RL, Reilly LM, Kerlan RK, Sawhney R, Jean-Claude J, et al. Abdominal aortic aneurysm in high-risk patients: short-to intermediate-term results of endovascular repair. Radiology 1999;210:361-5.
9. Zarins CK, White RA, Schwarten D, Kinney E, Diethrich EB, Hodgson KJ, et al. AneuRx stent graft versus open surgical repair of abdominal aortic aneurysms: multicenter prospective clinical trial. J Vasc Surg 1999;29:292-308.
10. Laheij RJ, Buth J, Harris PL, Moll FL, Stelter WJ, Verhoeven EL, et al. Need for secondary interventions after endovascular repair of abdominal aortic aneurysms. Intermediate-term follow-up results of a European collaborative registry (EUROSTAR). Br J Surg 2000;87:1666-73.
11. Naslund TC, Edwards WH Jr, Neuzil DF, Martin RS III, Snyder SO Jr, Mulherin JL Jr, et al. Technical complications of endovascular abdominal aortic aneurysm repair. J Vasc Surg 1997;26:502-10.
12. Kalliafas S, Albertini JN, Macierewicz J, Yusuf SW, Whitaker SC, Macsweeney ST, et al. Incidence and treatment of intraoperative technical problems during endovascular repair of complex abdominal aortic aneurysms. J Vasc Surg 2000;31:1185-92.
13. Boyle JR, Thompson MM, Clode-Baker EG, Green J, Bolia A, Fishwick G, et al. Torsion and kinking of unsupported aortic endografts: treatment by endovascular intervention. J Endovasc Surg 1998;5:216-21.
14. Becquemin JP, Lapie V, Favre JP, Rousseau H. Mid-term results of second generation bifurcated endovascular graft for abdominal aortic aneurysm repair: the French vanguard trial. J Vasc Surg 1999;30:209-18.
15. Chuter TA, Wendt G, Hopkinson BR, Scott RA, Risberg B, Kieffer E, et al. European experience with a system for bifurcated stent-graft insertion. J Endovasc Surg 1997;4:13-22.
16. Silberzweig JE, Marin ML, Hollier LH, Mitty HA, Parsons RE, Cooper JM, et al. Aortoiliac aneurysms: endoluminal repair- clinical evidence for a fully supported stent-graft. Radiology 1998;209:111-6.
17. White RA, Donayre CE, Walot I, Woody J, Kim N, Kopchok GE. Computed tomography assessment of abdominal aortic aneurysm morphology after endograft exclusion. J Vasc Surg 2001;33(2 Suppl):S1-10.
18. Umscheid T, Stelter WJ. Time-related alterations in shape, position, and structure of self-expanding, modular aortic stent-grafts: a 4-year single-center follow-up. J Endovasc Surg 1999;6:17-32.
19. Harris P, Brennan J, Martin J, Gould D, Bakran A, Gilling-Smith G, et al. Longitudinal aneurysm shrinkage following endovascular aortic aneurysm repair: a source of intermediate and late complications. J Endovasc Surg 1999;6:11-6.
20. Krohg-Sorenson KBM, Drolsum A, Kvernebo K. Periprosthetic leak and rupture after endovascular repair of abdominal aortic aneurysm: the significance of device design for long-term results. J Vasc Surg 1999; 29:1152-8.

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