Controversies in Technology

Optimal EVAR Fixation: Rebuttals

Rebuttal by Dieter Raithel, MD, PhD, et al

In his article "Suprarenal Stenting," Roy Greenberg, MD, strongly emphasized two key points—the necessity and safety of this technique. Regarding his section on "Necessity," migration is the point of focus for our rebuttal.

First, we think Dr. Greenberg has exaggerated the incidence of migration. If what he stated is true ". . . and has been noted to occur with nearly all endoprostheses. It is entirely possible that migration will be the ultimate failure mode for most endovascular repairs . . .," then his thoughts on the statement of Collin et al "Endovascular treatment of abdominal aortic aneurysms: a failed experiment," is illogical. In other words, if endovascular aortic aneurysm repair is a failed innovation in this circumstance, we would expect it to have been abandoned earlier. But, it is flourishing, and it is becoming increasingly popular with vascular surgeons, radiologists, cardiologists, and patients.

Second, prior to discussing migration, a consistent definition of migration is required. Of course, migration means endograft movement, but different investigators apply different standards (some define migration as movement >10 mm, whereas others define it as >5 mm), and different measurement methods (ie, renal artery, vertebral bone, CT, DSA), which is why several incidence rates of migration have been reported. It is also the reason that Dr. Greenberg et al[1] reappraised stent graft migration with a proposed revised definition. According to his revised definition, in his 24 cases of migration with SVS/AAVS standards, only 50% of the proximal migration was confirmed.

Third, the reasons responsible for migration lie in many aspects, which have been stated both in our article and by Greenberg et al.[1] Suprarenal fixation cannot ultimately prevent proximal migration—even a suprarenal stent within the visceral aortic segment does not necessarily confer ultimate stability.[2]

Fourth, we should be clear about the outcome of proximal migration. Does proximal migration mean complete and final failure? No! In the commentary to Dr. Greenberg's proposed revised definition,[1] Zarins[3] reported that 68% of the AneuRx cases with migration in the clinical trial did not require treatment and appeared to be stable over a follow-

*(**Dr. Raithel,** continues)*

Rebuttal by Roy K. Greenberg, MD

I read with interest my counterparts' opinions regarding the need for and safety of suprarenal stenting. Although there is an underlying logic to the plethora of hypothetical arguments posed by Dr. Raithel and his group regarding the safety of uncovered stents crossing the renal arteries, the statements are far from convincing. Allow me to reiterate four critical points:

1. Problems exist with current infrarenal fixation systems. The most widely used infrarenal graft in the US is the AneuRx. In Zarins' 6-year clinical update, 9.5% of the patients had migration of >10 mm by 4 years of follow-up.[1] Other investigators quote rates approaching 40% migration at similar time points[2,3] with the same device. This migration risk is unacceptable.

2. The suprarenal aorta is more stable than the infrarenal aorta. A multitude of studies have shown the propensity of the infrarenal neck to dilate.[4-6] The relatively lower incidence of aneurysms affecting the visceral aortic segments speaks to the truth to this concept.

3. Crossing the renal arteries with an uncovered stent is safe. Multicenter, core lab controlled trials comparing such a practice with infrarenal surgical repairs[7] have shown an absence of detrimental effects. Similarly, multicenter[8] with core lab analyses, and single-center comparisons[9,10] between infrarenal and suprarenal devices show no detrimental effects to the presence of suprarenal stents.

4. Suprarenal fixation will decrease the incidence of migration and subsequently the risk of rupture. The presentation of the Eurostar migration analysis by Dr. Buth clearly states that the absence of suprarenal fixation is associated with a marked risk increase for migration (publication pending). The 4-year follow-up of the data from the Zenith pivotal trial (publication pending) has no cases of migration >10 mm. I understand that the Talent device is also associated with a comparably low rate of migration.

Based upon these arguments and the absence of any credible data pertaining to the danger of suprarenal stenting, we must ask ourselves why would you not provide your patient with an endograft that will likely have more durable fixation over an extended follow-up period? The general medical community in Europe has already made this determina-

*(**Dr. Greenberg,** continues)*

*(**Dr. Raithel,** continued)*
up extending more than 7 years. Therefore, we hold that proximal migration does exist, and can still occur, even with suprarenal fixation. Our experience shows no significant difference between suprarenal and infrarenal fixation on migration. Additionally, more than 7 years of follow-up have demonstrated that migration occurrence does not mean final failure. Therefore, our argument is clear: suprarenal fixation is not necessary.

We found that most of the the data cited by Dr. Greenberg come from the early stages of EVAR, with the first or second generation of endografts, and with the inevitable learning curve. Just as he stated, "The devices were placed, in many cases, a significant distance below the renal arteries." But, with improvements in material, technology, and experience, we are seeing fewer migrations.

Dr. Greenberg also stresses the importance of active fixation hooks and crimps. We agree, but we consider this to be the key improvement in endograft design. For the deployment technique, we emphasize infrarenal fixation with zero distance to the renal artery orifice, which we call "in the renal fixation." Furthermore, with device modification and accumulation of experience, we can manage most of the infrarenal abdominal aortic aneurysms with suitable anatomies using infrarenal endograft fixation. We reiterate that suprarenal fixation is not necessary.

Regarding the section on "Safety," renal function is the focal point of our rebuttal. Dr. Greenberg states that "almost every major company in the interventional AAA arena has a device with a suprarenal stent" as proof of the safety of suprarenal stenting. We think this fact cannot prove the safety of this technique because popular trends can also be negative trends. Each company is trying to provide different kinds of products to meet the market. Until now, the published results with or without randomization had only short- to intermediate-term results. Although most of the outcomes showed no significant deviation between suprarenal and infrarenal fixation, we did have a higher incidence of renal infarction in 1,064 consecutive cases. Dr. Greenberg thinks atheroemboli is one of the culprits of renal dysfunction, but from where do atheroemboli come? There are more potential risks of suprarenal fixation; the more proximal the intervention is, the greater the risk of atheroembolization will be. Besides other disadvantages we have listed, we believe longer follow-up with a larger number of patients is necessary for the confirmation of the safety of suprarenal fixation. ■

1. Greenberg RK, Turc A, Haulon S, et al. Stent-graft migration: a reappraisal of analysis methods and proposed revised definition. J Endovasc Ther. 2004;11:353-363.
2. Lee JT, Lee J Aziz I, et al. Stent-graft migration following endovascular repair of aneurysms with large proximal necks: anatomical risk factors and long-term sequelae. J Endovasc Ther. 2002;9:652-664.
3. Zarins CK, Bloch DA, Crabtree T, et al. Stent graft migration after endovascular aneurysm repair: importance of proximal fixation. J Vasc Surg. 2003;38:1264-1272.

*(**Dr. Greenberg,** continued)*
tion—simply look at which devices were utilized in the EVAR and DREAM trials.

The answer to this question, if there is one, lies in the skills of individual physicians providing therapy. Single-center data are worthy of concern. An unusually high rate of renal infarction (in comparison to multicenter prospective trial reports) after placement of a suprarenal stent should raise some concern. This is particularly true when the data are viewed in the context of patients treated with infrarenal devices at the same institution. I do not have an explanation for these marked differences, but I do know that stent grafts with suprarenal fixation generally do not swim upstream. I also know that graft material placed over a renal artery will ultimately cause thrombosis of the vessel and consequent infarction. Yet, I would assume, based on the US prospective multicenter trial data for suprarenal devices, infrarenal devices, and open surgical repair, that the risks of renal events—whether they are infarcts, occlusion, or worsening renal function—are roughly equivalent. Therefore, there exists an unexplained mismatch. Regardless of the aforementioned points, in the setting of such an incidence of renal complications, and in the multiple randomized trials cautioning the treatment of small aneurysms, the question must be asked—should these patients be treated at all (with a mean AAA size of 4.9 cm)? Ultimately, these issues boil down to individual factors that must be considered in the context of a specific patient, a specific device, and the skills of an individual physician to establish good short- and long-term results.

Were I a patient with an infrarenal AAA larger than 5.5 cm, whose anatomy was amenable to an endovascular repair, I would desire such an approach. The device I would want implanted would be a device that incorporates a suprarenal fixation system, is associated with a low risk of migration, a low endoleak rate, and a minimal risk of aneurysmal growth. These are the fundamental concepts that will ensure the long-term success of endovascular aneurysm repair. ■

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2. Cao P, Verzini F, Zannetti S et al. Device migration after endoluminal abdominal aortic aneurysm repair: analysis of 113 cases with a minimum follow-up of 2 years. J Vasc Surg. 2002;35:229-235.
3. Connors MI, Sternberg WI, Carter G et al. Endograft migration one to four years after endovascular abdominal aortic aneurysm repair with the AneuRx device: a cautionary note. J Vasc Surg. 2002;36:476-484.
4. Matsumura J, Chaikof E. Continued expansion of aortic necks after endovascular repair of abdominal aortic aneurysms. EVT Investigators. Endovascular Technologies Inc. J Vasc Surg. 1998;28:422-430.
5. Illig K, Green R, Ouriel K et al. Fate of the proximal aortic cuff: implications for endovascular aneurysm repair. J Vasc Surg. 1997;26:492-499.
6. Sonesson B, Malina M, Ivancev K et al. Dilatation of the infrarenal aneurysm neck after endovascular exclusion of abdominal aortic aneurysm. J Endovasc Surg. 1998;5:195-200.
7. Greenberg RK, Chuter TA, Lawrence-Brown M et al. Analysis of renal function after aneurysm repair with a device using suprarenal fixation (Zenith AAA Endovascular Graft) in contrast to open surgical repair. J Vasc Surg. 2004;39:1219-1228.
8. Endovascular aneurysm repair with suprarenal versus infrarenal fixation: a controlled study of renal effects. 5 A.D. Jun 18; 2005.
9. Cayne N, Rhee S, Veith F et al. Does transrenal fixation of aortic endografts impair renal function? J Vasc Surg. 2003;38:639-644.
10. Alsac JM, Zarins CK, Heikkinen MA et al. The impact of aortic endografts on renal function. J Vasc Surg. 2005;41:926-930.