The Top Five TEVAR Papers of 2011

Roy K. Greenberg, MD, provides a look at five of the most important articles published in the thoracic endovascular repair field during the past year, summarizing each and offering commentary on their impact.

A few weeks ago, *Endovascular Today*'s Matt Pesotski asked me if I would be interested in writing an editorial evaluating the top five articles relating to thoracic endovascular repair (TEVAR) published in the past year. My first response was, "Sure, what are the articles?" Matt's answer was something along the lines of, "I'm not sure. Our goal would be to share your opinions as to what the most important TEVAR papers of 2011 were, and most importantly, to put their importance into context."

With all the literature published in a rapidly growing field over a given year, this wasn't going to be easy.

If one were to attempt to be scientific about such an assessment, a committee would be established, and the multitude of publications pertaining to the subject would be reviewed and scored in accordance with their importance to the field, scientific merit, and quality. However, that was not what was done for this editorial. Instead, I sat down at my computer and logged onto PubMed. The search criteria I used included "TEVAR" and "thoracic endovascular repair" in various permutations. The search was limited to publications in the last 12 months. This yielded 293 papers on the day I conducted the search, resulting in a long afternoon of abstract reviewing. I selected the 20 abstracts that appeared to me to be most significant—and then keeping with the rigorous scientific methods employed here, I supplemented the total with a few extra abstracts. With the help of my assistant, Sheila, I was able to obtain copies of all of the papers and review them.

The selection of the best papers was not focused solely on the quality of the paper or the science, although these played a strong role; it also involved an assessment of the impact or potential impact of the paper on the overall field of TEVAR. From these papers, I selected the top five I believed would be of interest to the readership of *Endovascular Today,* and there is only one episode of nepotism.

I was asked to summarize the articles, which I divided into two parts. The first section of each review is a summary of the data, and the second section is an extrapolation of the discussion and conclusions. Following that, in a bit of a tongue-in-cheek manner, is my editorial commentary. The articles are ranked from 1 to 5 and presented in the reverse order akin to David Letterman's Top Ten countdowns. Please understand that I may be exceptionally biased, I did not use rigorous science to arrive at these conclusions, this did not undergo peer review, and it was completed over a period of a few days. I apologize wholeheartedly if I neglected "your" article, or an article that is obviously more important than the ones I chose, but that is the nature of an editorial.

5 Endovascular Repair Compared With Operative Repair of Traumatic Rupture of the Thoracic Aorta: a Nonsystematic Review and Plea for Trauma-Specific Reporting Guidelines

Karmy-Jones R, Ferrigno L, Teso D, Long WB 3rd, Shackford S. *Journal of Trauma Injury, Infection and Critical Care (2011;71:1059–1072)*

DATA SUMMARY

The authors reviewed the PubMed literature looking for patients with traumatic aortic rupture or thoracic aortic injury from 2006 to 2010. Papers were reviewed to assess for the inclusion of specific criteria related to the anatomy of the injury, urgency of the repair, as well as other patient characteristics. The results, with respect to the completeness of reporting for trauma patients were dismal. Only 6.4% of the papers described the injured area of the aorta using standardized criteria, 26% reported the degree of the injury, 19% the urgency of the intervention, 32% the hemodynamic status of the patient at the time of repair, and 57% reported the associated injury severity score.

EXTRAPOLATED CONCLUSIONS

The shift from open repair (OR) to endovascular management of traumatic aortic injury is based on a perception that TEVAR is associated with a lower risk of morbidity and mortality. Yet there exists significant inherent bias in the

reports leading to this conclusion. Fundamentally, a great deal of data is lacking. The lack of reporting of critical measures precludes any real scientific comparison of the two treatments. Overall, results may have been skewed in favor of TEVAR because OR was more often performed in unstable patients, and TEVAR may have been used for lesser degrees of aortic injury. There were more strokes following TEVAR than OR, and this must be considered, and there is limited long-term follow-up from both groups. Ultimately, there is a place for TEVAR and OR in these patients.

EDITORIAL COMMENTARY

The data in this paper do not drive one to support the use of TEVAR or OR for aortic trauma, but rather represent a call for reporting standards and adherence to reporting standards by authors. The recent publication of the reporting standards for thoracic and thoracoabdominal aneurysm repair[1] provide some guidance in this regard, but do not include details of the trauma specific concerns. Thus, papers written on this subject should attempt to conform to both the endovascular reporting standards and the trauma reporting standards such that as complete a picture as possible is provided.

The lack of good studies on this subject becomes obvious when one reads the Society for Vascular Surgery clinical practice guidelines,[2] which note grade 2, level C evidence of TEVAR having a lower morbidity and mortality than OR. This is a fundamental problem in the literature surrounding EVAR and OR of thoracic diseases. It is a critical message to our societies that we must have sound methods of reporting data, allowing the interpretation of such data in a meaningful way.

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4 Endovascular Repair of Complicated Chronic Distal Aortic Dissection: Intermediate Outcomes and Complications

Kang WC, Greenberg RK, Mastracci TM, Eagleton MJ, Hernandez AV, Pujara AC, Roselli EE.
Journal of Thoracic and Cardiovascular Surgery (2011;142:1074–1083)

DATA SUMMARY

This retrospective review included 76 patients with chronic dissections. The indication for intervention was aneurysm > 5.5 cm or rapid growth over a 6-month period for approximately 75% of the patients. The time between the dissection and the endovascular intervention averaged 25 months, and the majority of the patients had dissections extending from the arch through the iliac arteries (61%). All patients were treated with nontapered thoracic endografts. Technical success was obtained in 96% of patients (three patients had proximal type I endoleaks). There were four early deaths that were related to complications prior to the procedure (one malperfusion) or the procedure itself (three patients). There was no paraplegia and one stroke.

At a mean follow-up time of over 36 months, only 15% of patients had aortic growth noted in the treated segment, mostly associated with persistent proximal endoleaks. The remainder of the patients had slow growth (mean, < 1 mm/year) of the segments distal to the stent graft–treated aorta in the setting of stable or shrinking treated segments. Complete false lumen thrombosis occurred in only a small number of patients with extensive dissections (13%) but was noted to occur commonly in the treated aorta (91%) when assessed by computed tomography employing both arterial and delayed phases. Over the course of follow-up, there were four retrograde proximal dissections. There were three cases of true lumen compression/collapse occurring at 6, 92, and 123 days after the procedure. All were successfully treated with ballooning (two) or an additional stent graft (one).

EXTRAPOLATED CONCLUSIONS

When aneurysmal degeneration is limited to the upper descending thoracic aorta, it appears that simple TEVAR is a reasonable option for limiting growth and rupture risk. An overall diameter reduction was noted in 85% of treated patients, and cases of growth were nearly always a result of persistent proximal endoleaks. The infrequent observation of stent graft compression in spite of the chronicity of the dissection coupled with the use of nontapered grafts implies that the true-to-false lumen relationship remains dynamic, allowing true lumen expansion after treatment with an endovascular stent graft. Issues remain with the proximal sealing zone, and devices specifically designed for this region will be helpful. The slow but continuous growth of the distal aorta is nearly uniform; thus, these patients must be followed for extensive periods of time.

EDITORIAL COMMENTARY

There has been long-standing debate as to what defines an acute versus a chronic dissection. Additional discussion continues about the evolving morphology of the membrane between the lumens. Surgical observations note that additional fenestrations appear, and the membrane between the two lumens thickens and stiffens over time. However, from an endovascular perspective, it appears that the membrane behaves in a similar fashion whether treated acutely or in the chronic stage. Thus, the need for tapered devices for chronic dissections (assuming that the true lumen may not expand) is likely overemphasized. This allows clinicians to simplify sizing (using only the proximal neck measurements), irrespective of the distal true lumen

diameter. If these results are achieved in larger studies, there become few relevant differences between acute and chronic dissections when treating the disease with a stent graft.

Such a concept would allow for the development of treatment paradigms to treat dissection patients when aneurysms occur rather than in a prophylactic manner. The later approach only seems justified because of a perceived difference in the ability to utilize endovascular means to prevent rupture in acute dissections and not in the chronically dissected aorta. The need for complex devices in this population, such as branched and fenestrated stent grafts, is the exception rather than the rule. However, the incidence of retrograde dissection in patients treated with stent grafts for acute or chronic dissections remains a concern. Whether this is an issue with the implant characteristics (eg, stiffness, active fixation, or uncovered proximal stents) or the disease itself remains to be determined. Clinicians clearly must carefully evaluate how these devices will sit within the proximal aorta with respect to the risk for proximal endoleaks, malapposition to the lesser or greater curvature, and radius of curvature.

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3 Staged Approach Prevents Spinal Cord Injury in Hybrid Surgical-Endovascular Thoracoabdominal Aortic Aneurysm Repair: an Experimental Model

Bischoff MS, Scheumann J, Brenner RM, Ladage D, Bodian CA, Kleinman G, Ellozy SH, Di Luozzo G, Etz CD, Griepp RB.

Annals of Thoracic Surgery (2011;92:138–146)

DATA SUMMARY

A porcine model was used to assess the effect of segmental artery (intercostal and lumbar) sacrifice on the potential to develop spinal cord ischemia (SCI). Twenty pigs were randomized into two groups of 10. The segmental arteries (SA) from T13 through L5 were occluded using surgical ligation, while those above T13, SA were occluded using an endovascular stent graft. Group 1 underwent occlusion of all SAs, while Group 2 underwent the same SA sacrifices in two stages, 1 week apart. Thus, the stent graft procedure was completed in the same setting as the SA surgical ligation for Group 1, and 1 week after the surgical ligation for Group 2. Hemodynamic monitoring included arterial lines for assessing the mean arterial pressure (MAP) as well as the collateral network pressure (CNP) using tunneled catheters. MAPs were maintained at 90 mm Hg or greater for 48 hours after the procedures. Neurologic and histopathologic details were studied.

Only 50% of the animals in Group 1 regained normal spinal cord function (as measured by the Tarlov score). The entire Group 2 regained normal spinal cord function. Baseline CNP was 74 mm Hg for both groups, which decreased to 41–43 mm Hg after lumbar SA sacrifice for both groups. After TEVAR in Group 1, the CNP dropped to 24 mm Hg, but by 5 days had increased to 69 mm Hg. The nadir CNP in Group 2 was reached 5 hours postoperatively at 36 mm Hg, but by 1 week had increased to 71 mm Hg, then dropping to 54 mm Hg after TEVAR. All of these differences were statistically significant. The histopathologic data correlated with the clinical data, yet even Group 2 had animals without clinical sequelae with predictable patterns of histologic evidence of ischemia.

EXTRAPOLATED CONCLUSIONS

Occlusion of the SAs leads to a sudden disruption of the blood supply to the spinal cord, resulting in a risk of SCI. Patients with aneurysms often have chronic occlusion of SAs resulting in a clinical scenario that differs from the porcine model, in which all SAs are patent until occluded. The CNP is a valid means of assessing spinal cord perfusion, and the drop in CNP can be mitigated by staging the occlusion of SAs. It also appears that the pattern of CNP diminution and recovery differs by the mechanism of occlusion (simultaneous occlusion of all SAs with TEVAR, versus the sequential surgical ligation of SA at 3-minute intervals). This was noted when the authors compared their data to a near-identical animal study evaluating open repair for thoracoabdominal aneurysms.[3]

They hypothesize that during the brief periods between surgical ligation of the SAs, some ischemic preconditioning of the spinal cord may occur, resulting in higher CNPs following surgical ligation compared with endovascular means of occlusion. Clinically, the authors believe that the utilization of specific controlled conditions favoring spinal cord protection (such as hypothermia, cerebrospinal fluid drainage, and maintenance of high MAPs) will mitigate the drop in CNP when high numbers of SAs are occluded at the same time. Thus, employing a two-staged approach and utilizing conditions favoring spinal cord protection will reduce the risk of SCI by allowing the CNP to recover to a more acceptable baseline level prior to occlusion of the second level of SAs.

EDITORIAL COMMENTARY

Dr. Griepp's group has contributed greatly to the understanding of SCI following aortic repair and continues to do so. Given that SCI is likely the most daunting complication related to thoracic or thoracoabdominal aneurysm repair, a more complete understanding of the pathways by which it manifests will undoubtedly help clinicians minimize future risks. This animal study helps to explain the importance and variables that affect the CNP. The debates that have gone on for years regarding the need for intercostal reimplantation,

the benefits of systemic or epidural hypothermia, and the optimal systemic blood pressures and continue today without definitive conclusions.

Now, we can add a focus on the pros and cons of staged procedures. Much like in the setting of elephant trunk grafts, which have been used to treat patients with arch and descending thoracic aneurysms, staged procedures in this setting will expose patients to a risk of rupture, complications precluding or delaying a second-stage procedure, and the need for multiple procedures. Is this offset by an associated risk reduction for SCI? At our institution, we certainly believe that staged procedures are of benefit in many patients with extensive aneurysmal disease with regard to the risks of SCI, but also by mitigating the response to extremely long segments of aortic replacement on the coagulation and inflammatory systems as well. The evidence presented in this study should cause clinicians to seriously consider staging the extent of SA coverage for patients undergoing extensive TEVAR procedures.

2 Endovascular Versus Open Repair of Ruptured Descending Thoracic Aortic Aneurysms: a Nationwide Risk-Adjusted Study of 923 Patients

Gopaldas RR, Dao TK, Lemaire SA, Huh J, Coselli JS. *Journal of Thoracic and Cardiovascular Surgery (2011;142:1010–1017)*

DATA SUMMARY

The Nationwide Inpatient Sample (NIS) data set was used to identify 923 patients treated for ruptured descending thoracic aneurysms (2006–2008). The Deyo score (a modification of the Charlson Index, which is a weighted comorbidity scoring system originally used for spine surgery patients) was used to provide a means of adjusting the morbidities of the TEVAR and open aortic repair (OAR) patients. TEVAR was used in 39% and OAR in 61%. The authors employed a multivariable regression analysis to compare the outcomes of TEVAR versus OAR after adjusting for potential confounding factors. In-hospital mortality, complications, failure to rescue (mortality among patients in whom a complication develops, termed *FTR*), and discharge disposition were compared. The unadjusted mortality was 23% for TEVAR and 29% for OAR, and after risk adjustment, there were no differences in the outcomes assessed between the two therapies with the exception of discharge disposition.

With regard to discharge, patients undergoing TEVAR were three times more likely to be discharged to home than OAR patients. A backward stepwise regression model was used to assess outcomes specific to TEVAR or OAR. Interestingly, hospital bed size was not associated with a greater mortality risk, complications, or FTR for patients treated with TEVAR, but all risks were higher for smaller hospitals employing OAR. Patients treated by TEVAR did have higher mortality and FTR in the setting of renal disease.

EXTRAPOLATED CONCLUSIONS

Most of the unadjusted outcomes between TEVAR and OAR were not different, but the TEVAR group had a higher proportion of routine home discharges than OAR. Fundamentally, the authors felt that the two therapies were relatively equivalent. Treatment with OAR in smaller hospitals was associated with a greater risk of complications, but that was not the case for the TEVAR group. However, TEVAR was performed at a smaller number of hospitals than OAR. These observations were attributed to the relative lack of expertise in cardiac surgical, operating room, and intensive care unit personnel seen in smaller hospitals compared to larger institutions. In contrast, the near-ubiquitous presence of cardiac catheterization laboratories or hybrid endovascular suites in all hospitals provides better support staff for TEVAR, allowing these cases to be done safely in such places.

Overall, the authors felt that larger institutions were equally competent in both techniques. Therefore, OAR should be avoided at smaller hospitals, and if the anatomy is reasonable and appropriate personnel are available, TEVAR may be considered. However, if transfer to a larger facility can be accomplished, then that would be the most desirable course of action because of the possibility that conversion from TEVAR to OAR may be necessary. The authors acknowledged several study weaknesses, including issues with coding errors, the limitations of relying solely on ICD-9-CM codes, the lack of information in the NIS database regarding readmissions, reinterventions and long-term outcomes, and issues with an inability to account for case volume, surgeon specialty, and surgeon volume.

EDITORIAL COMMENTARY

The ability to derive meaningful data from nationwide databases on specific topics is limited; however, this paper is important for several reasons. Gore & Associates (Flagstaff, AZ) received commercial approval from the US Food and Drug Administration to market the Gore TAG graft on March 24, 2005, for elective TEVAR with certain anatomic restrictions. The Zenith TX2 graft (Cook Medical, Bloomington, IN) was approved in 2008. The mining of the NIS began less than a year after the TAG approval. Thus, a comparison was made between conventional surgery—a mature and widely disseminated means of treating ruptured descending thoracic aneurysms—and the off-label use of a newly developed, narrowly disseminated technology that was found to yield equivalent (or better, if one considers being discharged to home rather than rehabilitation or nursing facility a good outcome) results to OAR.

Throughout 3 years of sampling, the percentage of patients treated with TEVAR increased from 31% to 47%, indicative of the increasing dissemination of TEVAR technology. Is it relevant to compare the commercial use of new technologies in an off-label indication to gold standards? That depends on the results of the study. If OAR outperforms TEVAR, it continues to be the treatment of choice. If TEVAR outperforms OAR, then it is an option, but we need long-term results (and it is still off-label).

The analysis of the data within the manuscript also deserves some commentary. Table 1 in the paper describes the baseline characteristics of the two groups. The TEVAR patients were older than the OAR patients by 7 years. In a nearly universal manner, the TEVAR group was sicker than the OAR group. The Deyo score was used to adjust these differences. Ideally, an analysis such as this would have enough data and well-measured variables to internally adjust for risk-tailored differences that are specific to outcome measures, such as a propensity score.

In the absence of an adequate size and appropriate details in the data set, the weighted comorbidity score (which was developed from a "presumably" relevant patient population) was used to adjust risk. The Deyo score does not take into account hemodynamic stability, need for transfusions, or any anatomic variables, all of which are considered critical when assessing outcome in such patients. Do generalized comorbidity scoring systems have any relevance when assessing a problem such as ruptured descending thoracic aneurysms?

Further issues include the fact that exclusion of OAR patients who required circulatory arrest based on the procedure codes likely produced better outcomes for the surgical population; however, such patients may not be anatomically suitable for TEVAR either. The definitions of complications also require attention. Why were there more respiratory complications in the TEVAR group—an observation that is very counterintuitive? Respiratory complications included pleural effusions, hemothorax, or any later intervention required to treat such issues. It seems to make sense that ruptured aneurysm patients would have a hemothorax. After open surgery, it is drained and chest tubes are placed, while after TEVAR, these "secondary" procedures usually occur at a later time.

The authors of this article hail from one of the most prestigious aortic centers in the world, and they must be applauded for their analysis in spite of any of the aforementioned shortcomings. The fact that TEVAR was no worse, and often better, than OAR within 1 year of commercial release in the United States says a lot. The ability for smaller hospitals to achieve results similar to larger institutions for ruptured descending thoracic aneurysms is also an important message. Both conclusions highlight the success of this technology with respect to the gold standard in a disease state that is associated with terrible outcomes.

Like most academicians, the authors expressed a need to see the results of a prospective randomized trial for such problems. I seriously doubt that clinicians and institutions will be able to overcome impediments of trial designs for ruptured thoracic aneurysms, including consenting in emergency situations, the ability to provide teams capable of both treatment methods, the relatively small number of patients presenting with this problem, and the ability to convince patients and families that open surgery is a choice when TEVAR is an option. These data will probably be the best that we get for a while.

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1 Transcatheter Aortic-Valve Implantation (TAVI) for Aortic Stenosis in Patients Who Cannot Undergo Surgery

Leon MB, Smith CR, Mack M, Miller DC, Moses JW, Svensson LG, Tuzcu EM, Webb JG, Fontana GP, Makkar RR, Brown DL, Block PC, Guyton RA, Pichard AD, Bavaria JE, Herrmann HC, Douglas PS, Petersen JL, Akin JJ, Anderson WN, Wang D, Pocock S; PARTNER Trial Investigators
The New England Journal of Medicine
(2010;363:1597–1607)

DATA SUMMARY

This was a randomized trial of patients with severe aortic stenosis who were considered nonsurgical candidates and underwent standard therapy versus treatment with the Sapien heart valve system (Edwards Lifesciences, Irvine, CA). Severe aortic stenosis was defined as an aortic-valve area < 0.8 cm^2, a mean aortic-valve gradient of > 40 mm Hg, or a peak aortic-jet velocity > 4 m/s. Patients were considered not to be candidates for open surgical repair when they had coexisting conditions that would be associated with a predicted probability of 50% or more of either death within 30 days or a serious irreversible condition by at least two surgeon investigators.

There were 3,105 patients screened, and 12% underwent randomization. Devices were 23 mm (22 F) or 26 mm (24 F) and deployed following balloon valvuloplasty using rapid right ventricular pacing. There was a coprimary endpoint of time to death from any cause or time to first occurrence of repeat hospitalization due to valve-related or procedure-related clinical deterioration. The study was powered by assuming a 1-year mortality of 37.5% in the standard-treatment group and 25% in the TAVI group. After randomization, the median time to TAVI was 6 days, with only six patients not receiving a valve. In the standard therapy group, 64% were treated with balloon valvuloplasty within 30 days of randomization and 20% subsequently.

The 30-day mortality rates were 5% and 2.8% (TAVI vs standard treatment, respectively). At 1 year, the mortality rates were 31% and 51%, respectively ($P < .001$). Cardiovascular-specific death at 1 year was lower in the TAVI group (21% vs 45%). Major strokes were more frequent in the TAVI group at 30 days (5% vs 1%) and 1 year (8% vs 4%). Vascular complications occurred in 31% (16% major complications) of TAVI patients compared with 5% (1% major complications) in the standard therapy group. The mean valve area in TAVI patients increased from 0.6 ± 0.2 cm^2 to 1.5 ± 0. 5 cm^2 at 30 days. Moderate-to-severe paravalvular aortic regurgitation was present in 12% of the TAVI group at 30 days and 11% at 1 year. Transvalvular aortic regurgitation was noted in 1.3% and 4.2% of TAVI patients at 30 days and 1 year versus 17% and 15% of standard therapy patients at similar time points.

EXTRAPOLATED CONCLUSIONS

Standard medical therapy did not alter the natural history of severe aortic stenosis through 1 year. Transfemoral TAVI was superior to standard therapy, markedly reducing the death from any cause or cardiovascular causes and repeat hospitalization through 1 year. Based on these data, only five patients need to be treated with TAVI to prevent one death at 1 year. The periprocedural rate of death for TAVI patients was not significantly different than the rate of death for patients undergoing standard therapy.

TAVI was associated with a significant reduction in symptoms as assessed with the New York Heart Association classification system and a 6-minute walking test. There were more strokes, vascular complications, and bleeding in the TAVI group. The echocardiographic findings confirmed good hemodynamic performance of the bioprosthetic valve—although there was a significant risk of paravalvular regurgitation after TAVI. The ongoing studies with lower-profile systems will likely reduce the risk of bleeding and vascular complications. Strokes remain a troublesome problem after TAVI and result primarily from atherothrombotic emboli.

EDITORIAL COMMENTARY

The PARTNER group must be commended for running a time-intensive well-designed clinical trial that spans two specialties: interventional cardiology and cardiac surgery. Like any trial, there are some design flaws and questions. Some would question the use of balloon valvuloplasty in the standard therapy group, as that treatment remains unproven.

There remain several cost-effectiveness questions relating to the absolute amount of life-years gained, coupled with any improvement in quality-of-life outcomes, as well as an increased risk of stroke, which does not appear to be limited to the periprocedural period. Why were there significant baseline differences between the groups in a randomized trial—such as a higher logistic EuroSCORE, greater incidence of chronic obstructive pulmonary disease, and atrial fibrillation—between the standard therapy group compared with the TAVI group? Do those factors increase the perceived benefit of TAVI with respect to mortality? How accurate were the surgical assessments with regard to labeling patients as nonoperative candidates? Is this akin to issues that we saw in EVAR-2? In fact, 10 patients who were considered inoperable did undergo procedures, and six died, an observation that supports the methods by which patients were risk-adjusted.

Overall, this new technology, which is now commercially available in the United States, likely heralds a paradigm shift in patient management. From the vascular surgical perspective, it reminds me of a scene from the 1982 movie *Poltergeist* where Carol Anne awakens and stares into the static-glowing TV set in her parents' bedroom and utters the memorable words: "They're here."

The commercialization of percutaneous valves provides a drive for cardiologists and cardiac surgeons to become intimately familiar with many of the techniques required for successful TEVAR. One can only postulate that serial advances with this technology coupled with endovascular grafts will be used to treat more complex conditions and ultimately become part of a series of endeavors that will replace open surgery for the valve, coronary arteries, aortic root and beyond. Which specialty will be most suited to developing these technologies? Where will they be performed?

In terms of the most influential papers on TEVAR during the past year, I think this one wins the prize. ■

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