

Endovascular Treatment of Thoracic Aorta Lesions: an Update

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During the last decade medical professionals have been witnessing steady technological advances in diagnostic imaging techniques and therapeutic processes. Consequently, we now have available new minimally invasive techniques which are a good alternative to more conventional surgical procedures. Vascular diseases have also benefited from this inexorable trend. Thoracic aorta diseases may be those that could gain the most from these new approaches, since the gain in benefit is greater regarding reducing morbidity and mortality. But what do we know for certain? We think it would be sensible to inform the reader about the current situation before being carried away with unrestrained and sometimes irrational enthusiasm. Thus, we are grateful for the opportunity to describe our current knowledge concerning endovascular treatment of lesions of the thoracic aorta.

THE BACKGROUND

It is not surprising that, in the 21st century, new and less invasive therapeutic methods with the same or better efficacy than the more conventional surgical techniques should be sought and developed for the treatment of aortic lesions. In this regard, endovascular surgery or therapy is the main focus of interest for treating the complex and increasingly prevalent arterial diseases. In our opinion, it is more accurate to speak in generic terms about endovascular treatment than of percutaneous treatment. Even in the original article that appears in this issue of the Journal, the specific therapeutic approach described is surgical incision and dissection of the femoral artery rather than a

percutaneous procedure.¹ Thus, before continuing, it would be useful to define endovascular treatment as that therapeutic action by which the repair of a distant vascular segment is achieved, using a remote vascular entry point, either percutaneous or via dissection, and catheterization techniques. The monitoring method is usually fluoroscopy (radioscopy).

A small but important historical point is that, although the first clinical experience of endovascular repair of aneurysms of the abdominal aorta is attributed to the surgeon Juan Carlos Parodi in 1990,² it was at the end of 1986 when a Ukrainian surgeon, Nicolai Volodos, carried out the first endovascular repair of a pseudoaneurysm of the descending thoracic aorta.³ To this end he built a "home-made" stent out of some Gianturco stents and covered them with a polyester vascular prosthesis. Its publication in Russian in 1988 did not have the same impact as that of the American radiologist from Stanford University, Michel Dake, who monopolized attention some years later. In 1994, Dake et al published their first series of patients with lesions of the descending thoracic aorta treated with "home-made" stents⁴ in a leading medical journal (*New England Journal of Medicine*). Since then, and to date, it is estimated that more than 10 000 commercial thoracic stents have been implanted throughout the world (400 of them in Spain).

THE PROFESSIONAL IMPACT

This new therapeutic method was not uniformly adopted by teams, centers, or hospitals. Thus, the arrival of these revolutionary endovascular techniques, and more specifically, those concerning the aorta, led to 3 types of clinical and professional scenarios. This was due to the involvement of several specialties in the endovascular technique. On the one hand, the patient is selected by a specialist team. The process of diagnostic imaging is done by another team of specialists. Finally, catheterization techniques and fluoroscopy have always been the jurisdiction of other professionals. Hence, different

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institutions or settings throughout the world have dealt with potential interdisciplinary conflicts that could arise in different ways.

The first scenario involves rejection or deep skepticism on the part of the professionals in charge of the patients who might potentially benefit from this treatment. Such behavior has not aided in the development of the new technologies, neither within the institutions nor outside them, whereas it has fueled conflict among professionals due to disagreements regarding the actual approach. The second scenario is characterized by simply adopting the new techniques, thus following a self-taught approach, and directly applying them to their own patients. In this situation, interdisciplinary conflicts and fights, in addition to hindering interprofessional relationships, have prevented patients from receiving the best care and delayed the implementation of the new techniques, thus involving long learning curves which sometimes have not led to optimal results. The third scenario evolved from joint efforts and experiences around the patient, that is, the creation of multidisciplinary teams led by a person in charge, a clinical coordinator. This latter solution has fostered interprofessional relationships, reduced learning curves, and yielded better results. This alternative is the one recommended by health authorities, pioneering groups and the companies manufacturing endovascular products. This is the option adopted by our institution, as well as by the authors of the article published in this issue of the *Journal*.¹ It is of special interest to consider that several professionals are involved in the therapeutic process from diagnosis, patient selection, and the procedure itself, to post-therapeutic follow-up. All these stages are equally important to ensure technical and clinical success and should be applied with equal attention, dedication and professionalism. In our center, the multidisciplinary team for endovascular therapy of the thoracic aorta is made up of a vascular surgeon, a cardiac surgeon, a cardiovascular anesthesiologist, an interventional vascular radiologist, a transesophageal echocardiography expert (cardiologist), a vascular imaging expert (computerized tomography and magnetic resonance imaging), cardiovascular surgery nursing personnel, qualified technicians in interventional vascular radiology and even an economist in charge of the financial-administrative aspects of cardiovascular management. All of them are dedicated participants in the different processes entailed by endovascular treatment of the thoracic aorta.

In line with this, we see the emergence of teams involved in the treatment of the thoracic aorta which is giving rise to changes in professional attitudes. This is another direct consequence of the implementation of endovascular techniques and their application to this disease which in very recent times

was restricted to a few tertiary health centers, called referral centers. Many centers currently exist that, without previous or with limited experience in thoracic aorta surgery, are daring to implant stents in this anatomical area. Doubtless this fact also has implications regarding the relationships between different specialties. Some have even proposed a change in the orientation of the specialties and the future training of specialists around these new endovascular techniques.

If we focus on aortic disease, specifically aneurysms, which involves 5%-10% of the male patients over 65 years old and is implicitly life-threatening, we can appreciate that any solution or improvement in its diagnosis, and especially in its treatment, would be welcomed by all the professionals directly or indirectly involved with this pathological process and, obviously, by the patients who suffer from it. However, if we focus on the thoracic aorta, in addition to degenerative aneurysms, we can include other diseases with a catastrophic evolution and moderately beneficial surgical treatment carrying high morbidity and mortality (depending on the series, a mortality of 4%-40% and paraplegia of up to 18%).⁵⁻⁸ We are referring here to acute aortic syndrome (acute type B dissection, penetrating ulcer, intramural hematoma), lesions, pseudoaneurysms, chronic type B dissections, and aortobronchial or aortoesophageal fistulas. All of these can be potentially managed with endovascular treatment. Thus, endovascular treatment of the thoracic aorta is especially attractive to patients and physicians. Obviously, it is also economically attractive to the industry that manufactures and markets the stents, whose price ranges between 6000 and 15 000 euros, although this clearly does not have the same attraction for those who are responsible for finances, such as the health administrations. The current panorama of thoracic aorta stents is completed by the absence of sufficient medical evidence for their broad recommendation as the first choice of treatment. However, in Europe, some 5 brands have been marketed with the EC label (European Community) and very soon 2 models will be approved by the Food and Drug Administration (FDA) in the United States.

THE PROCEDURES

As is well known, surgery of the descending thoracic aorta involves high mortality and morbidity rates that surpass those of the abdominal aorta. Paraplegia presents the highest morbidity related to conventional surgical treatment of the descending thoracic aorta, with rates ranging from 0% to 18% depending on the series cited.⁵⁻⁸ Furthermore, degenerative aneurysmatic disease is not the only

disease that can benefit from repair. As mentioned before, there is a list of diseases that have unsatisfactory surgical outcomes that could be treated with endovascular techniques. Furthermore, if hybrid techniques combining conventional surgery with endovascular techniques are used, any segment of the thoracic aorta can be treated, although it has to be accepted that this incurs greater risk due to use of conventional surgical techniques.

As conventional surgery of the thoracic aorta is a high-risk procedure, the endovascular technique has gained greater popularity in the thoracic part, in patients in a generally better state, than in the abdominal part. In other words, when the surgical risk involved in surgical repair exceeds what traditionally has been considered reasonable, endovascular treatment is preferred, especially in those centers with experience. In addition, modern diagnostic methods favor the detection of unknown or subdiagnostic aortic diseases (penetrating ulcer, intramural hematoma, injury to the aorta, chronic dissections, etc). If endovascular treatment were not available, it would be indeed very difficult to manage all of them via surgical procedures.^{9,10}

There is a general consensus regarding the repair of thoracic aortic aneurysms with a diameter ≥ 6 cm. Symptomatic type B dissections are another clear indication. Chronic dissections that also generate aneurysms or symptoms need to be treated. However, there is no agreement regarding systematic repair of acute asymptomatic dissections and only medical treatment is offered. Neither has it been possible to obtain general agreement regarding a definitive procedure for penetrating ulcers or intramural hematomas. Typical injuries in the aortic isthmus are better managed with endovascular treatment in the context of patients suffering multiple trauma.¹¹ Procedures regarding aortobronchial or aorto-esophageal fistulas, where typical septic complications can limit the benefit of endovascular treatment, are more controversial but some specific successful cases have been reported (Riambau et al, personal communication to the National Congress of the Spanish Society of Angiology and Vascular Surgery, Madrid, 2002).

In addition, the cost-effectiveness of stents in these types of disease is now better understood, given that they offer a less invasive and more effective alternative, at least in the medium term, and are also less expensive than traditional surgical methods. For example, endovascular repair in the third section of the descending thoracic aorta can be carried out under local anesthesia, with a surgical time <1 h, no consumption of blood derivatives nor special beds, a stay <48 h and the patient's almost immediate physical recovery. However, uncertainty regarding the durability of this method is the strongest argument its

critics put forward, and it is really the limiting factor of the technique itself. Stent durability determines the need for reinterventions which doubtless has reduced the number of indications, making their use a matter of concern in young patients, such as those suffering multiple trauma. However, we expect that the technology supporting endovascular treatment will continue to develop, such that the endovascular technique as the treatment of choice can be consolidated without having to take so many precautions.

As is the case with abdominal stents, candidate patients should meet certain anatomical or morphometric requirements to be able to safely anchor the stent without occluding essential branches of the thoracic aorta (coronary artery, supra-aortic trunks, visceral branches, medullary artery) and to gain access from the femoral arteries. Thus, what is required is a >20 -mm-long proximal segment, no wider than 40 mm, a 20-mm-long distal segment and iliac arteries with little tortuosity and without aneurysms, calcium or thrombus in their walls, in order to be able to navigate through them with introducers with a caliber higher than those used for abdominal stents (22-25 Fr). However, these anatomical restrictions have changed thanks to the experience gained in recent years. Thus, the left subclavian artery can be covered intentionally and safely without the need for preventive revascularization, as long as there is no dominant left vertebral artery, no mammary bypass is dependant on it, the right subclavian artery does not originate distal to the left subclavian artery and the patient is not left-handed.¹² The possibility of carrying out combined or hybrid surgery makes it possible to include the origins of the supra-aortic trunks if extraanatomical or anatomical revascularizations had been done previously to ensure flow to the brachycephalic trunk and left carotid artery. In the same way, thoraco-abdominal aneurysms can be treated if the patient's condition allows for revascularization of the visceral branches from the abdominal aorta or from the common iliac trunk. Furthermore, the number of access points can be increased if retroperitoneal approaches to the terminal abdominal aorta or the common iliac trunk are employed with the placement of provisional stents. As an exception we can use an antegrade route from the ascending aorta or the ascending arch or from the upper descending aorta to treat lesions with stenting which cannot be reached from the iliofemoral area. In fact, there is less variety of stents available for the thoracic part than for the abdominal which have been approved by the European Community. Currently, only 5 brands are available: Talent® (Medtronic, Santa Rosa, USA), Excluder TAG® (W.L. Gore & Associates, Flagstaff, USA), Endofit® (Endomed, Phoenix, USA), Zenith® (Cook, Bloomington, USA),

and Evita® (Jotec, Lotzenäcker, Germany). The Relay® stent (Bolton, Sunrise, USA) is expected to come into use at the beginning of 2005. This is currently available for compassionate use in Europe. Approval of the Excluder TAG® stent by the FDA is expected in the first quarter of 2005. This will probably be followed by the Talent® stent at the end of 2005.

Finally, candidate patients should be aware of the experimental character of the technique and thus should provide specific informed consent, with full understanding of the results of the new technique and those of conventional surgical or medical alternatives. This is the most sensitive but unavoidable part of the entire selection process and procedure. Without accurate and impartial information, and consequent consent by the patient, ethically speaking, we cannot proceed with any treatment and even less with endovascular repair of the aorta. Thus, it is advisable that endovascular treatment is evaluated and accepted by the ethics committee of each center.

THE RESULTS

It is not easy to speak about global results based on the published cases or series of cases in individual centers. The best approach may be to describe the results of the EUROSTAR European multicenter registry since, despite its recognized limitations as a voluntary registry, it provides a more realistic picture of the current clinical situation in our geographical area. EUROSTAR initiated the prospective inclusion of thoracic aorta stent cases in January 2000. It has also included a small number of retrospective cases since 1999. A total of 476 patients from 54 European hospital centers has been included in the EUROSTAR thoracic registry (EUROSTAR Progress Report for August 2004) up to August 2004. Most of them presented atherosclerotic disease (250 patients); 131 presented type B dissection (73 chronic and 58 acute); 59 presented trauma injuries (32 chronic and 27 acute); 16 presented false aneurysms; and 11 presented penetrating ulcers. Technical success was achieved in 92% of the cases. Eight per cent presented some type of immediate leak. Intraoperative changeovers to conventional surgery were reported in 0.8% of cases. Paraplegia occurred in 1.6% of cases, paraparesis in 1.05%, and stroke in 2.4% due to manipulation of the aortic arch with guides and catheters. Global hospital mortality was 11.3%.

The short- and medium-term results of EUROSTAR yielded a cumulative survival at 3 years of 76.4%. The absence of persistent leaks was 99.3%. The absence of secondary interventions, also at 3 years, was around 84%.

Our center's results are slightly better than those recorded in EUROSTAR, to which we also actively contributed our data. Thus, our personal experience

from March 1997 to March 2004 covered 102 patients treated with the implantation of thoracic stents, the majority for degenerative aneurysm (56%). Other lesions treated with stents included: chronic type B dissections (18%), acute type B dissections (7%), trauma (9%), penetrating ulcers (5%), aortobronchial fistula (1%), and stenosis (2%).

Immediate technical and clinical success reached 97.3% for these thoracic lesions. Only one patient required admission to the intensive care unit due to a postoperative lung infection related to the procedure. The mean postoperative stay was 50 h, the need for transfusion was minimal and global mortality was 2.9%. One patient died due to liver rupture in the context of multiple trauma, one due to ileac rupture and one due to myocardial infarction. Fortunately, no paraplegia nor changeover to conventional surgery was reported in our series. Combined surgery was necessary in 27% of the patients (3 ascending aorta repairs, 6 carotid-carotid bypasses, 3 carotid-subclavian bypasses, 1 visceral transposition, 1 complete transposition of the supra-aortic trunks, and 13 retroperitoneal approaches). During our follow-up, the cumulative survival rate was 85% at 3 years and the cumulative rate of absence of persistent leaks was 99%. The cumulative absence of reinterventions was 87.5% with 2 type III leaks (at 2 and 28 months) and 1 type I (at 6 months).

Although the initial results are encouraging and promising, solutions to some of the restrictions preventing the more general use of this technique and its extension to other procedures are still pending.

PENDING ISSUES

A cause for concern is material fatigue which occurs with abdominal aorta stents and, to a lesser extent, in thoracic aorta stents. Apparently, bifurcated stents in the abdominal part undergo greater shear stress forces than in the thoracic part. However, we have to ensure the durability of stent components as they have to be used in young patients (e.g., dissections, trauma). Another aspect that should be improved is the possibility of applying them in pathological areas involving the aortic arch. To this end we need more flexible stents, with fenestrations or branches and with safer delivery systems.

One subject that remains unresolved is the behavior of patent false lumen due to distal reentries in type B dissections affecting the visceral branches. The arrival of fenestrated stents or those with branches may help to solve this problem. It also remains to be clarified whether the current procedures for repair of aortic lesions can be expanded and whether it would be acceptable and advisable to use stents as the treatment of choice for intramural hematomas, all penetrating ulcers, all

type B dissections, and for chest trauma. It will probably be necessary to wait for a while until clinical experience, supported by the technology, can better justify this therapeutic alternative.

Finally, and no less importantly, the price of the procedure and the attitude of the health care systems are unresolved issues, as in the case of abdominal aorta stents, but this is outside the scope of the present article.

THE FUTURE

It is reasonable to say that whether the future will be bright or otherwise will depend on the ability to resolve the current restrictions and dilemmas we have outlined here. It is highly probable that different stent designs would be needed depending on the thoracic disease to be treated. Treating a degenerative aneurysm is not the same as treating an acute dissection. The type of support and positioning should be differentiated. Stents with fenestrations and branches for the visceral arteries or supra-aortic trunks will become available, although the technological complexity involved in their implantation means they will be expensive. Meanwhile, and in the near future, hybrid or combined surgery seems an acceptable intermediate solution that can be applied to the great majority of complex cases. However, when introducing conventional surgical elements, we have to expect greater mortality and morbidity than when using purely endovascular treatment.

Given increasing technical complexity, we can expect the emergence of super-specialized teams in this area. In order to maintain a high degree of excellence, these techniques demand continuous

practice and this will be only possible for teams capable of managing aorta disease in a comprehensive way, (i.e. diagnostic, medical, surgical, and endovascular issues). Once again, and emphasizing the message outlined by Martín et al in their article, multidisciplinary units will be the ones best suited to the management of the aorta in the near future.

REFERENCES

1. Martín M, Morís C, Lozano I, Llana JM, Vega F, Fernández F, et al. Tratamiento percutáneo de las afecciones de la aorta torácica. Una labor multidisciplinaria. *Rev Esp Cardiol.* 2005;58:27-33.
2. Parodi JC, Palmaz JC, Barone HD. Transfemoral intraluminal graft implantation for abdominal aortic aneurysms. *Ann Vasc Surg.* 1991;5:491-9.
3. Volodos NL, Karpovich IP, Shekhanin VE, Troian VI, Iakovenko LF. A case of distant transfemoral endoprosthesis of the thoracic artery using a self-fixing synthetic prosthesis in traumatic aneurysm. *Grudn Khir.* 1988;(6):84-6.
4. Dake M, Miller CD, Semba CP, Mitchell RS, Walker PJ, Laddell RP. Transluminal placement of endovascular stent-grafts for the treatment of descending thoracic aortic aneurysms. *N Engl J Med.* 1994;331:1729-34.
5. Cambria RP, Clouse WD, Davison JK, Dunn PF, Corey M, Dorer D. Thoracoabdominal aneurysm repair: results with 337 operations performed over a 15-year interval. *Ann Surg.* 2002;236: 471-9.
6. Kouchoukos NT, Dougenis D. Surgery of thoracic aorta. *N Engl J Med.* 1997;26:1876-88.
7. Gravereaux E, Faries PL, Burks JA, Latessa V, Spielvogel D, Hollier LH, et al. Risk of spinal cord ischemia after endograft repair of thoracic aortic aneurysms. *J Vasc Surg.* 2001;34:997-1003.
8. Svensson LG. Natural history on aneurysms of the descending and thoracoabdominal aorta. *J Card Surg.* 1997;12 Suppl:279-84.
9. Riambau V, García-Madrid C, Castella M, Caserta G, Uriarte C, Josa M, et al. Results of endovascular repair of aortic penetrating ulcers and intramural haematomas. In: Amor M, Bergeron P, Castriota F, Mathias K, Raitel D, editors. *Thoracic aorta endografting.* Marseille: Com&Co; 2004. p. 217-23.
10. Evangelista Masip A. Historia natural y tratamiento del síndrome aórtico agudo. *Rev Esp Cardiol.* 2004;57:667-79.
11. Ott MC, Stewart TC, Lawlor DK, Gray DK, Forbes TL. Management of blunt thoracic aortic injuries: endovascular stents versus open repair. *J Trauma.* 2004;56:565-70.
12. Riambau V, Caserta G, García-Madrid C, Uriarte C, Castellá, M, Josa M, et al. When to revascularize the subclavian artery in aortic thoracic stenting. In: Brachereau A, Jacobs M, editors. *Hybrid vascular procedures.* New York: Futura-Blackwell; 2004. p. 85-9.