

Tirone on Tirone David operation and types

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Received: 7 May 2017 / Accepted: 12 August 2017 / Published online: 28 August 2017
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Keywords Aortic valve · Aortic valve insufficiency · Aortic root aneurysm · David operation

Historical perspective

Innovative surgical procedures often arise from foundations of knowledge and experiences with established operations. Aortic valve sparing operation was one of this stepwise, evolutionary procedure. Because there is no perfect heart valve substitute I have always tried to repair rather than replace heart valves whenever feasible. The most common lesion in aortic valve disease in adult patients, aortic stenosis, is not suitable for repair, and replacement is necessary, and for several decades the choices have been mechanical or tissue valves. I had been using aortic valve homograft for aortic valve replacement right from the beginning of my practice but procurement and supply was a limiting factor to expand its use. This was the impetus to develop stentless porcine aortic valves [1, 2]. Implantation of biological valves (aortic homograft, pulmonary autograft or stentless porcine aortic valves) in the sub-coronary position requires a sound knowledge of functional anatomy of the aortic root. Another operation that I performed from the beginning of my practice was aortic valve repair for aortic insufficiency due to prolapse of a cusp, mostly in young patients with bicuspid aortic

valve. With that foundation of knowledge and experience, it was not difficult to evolve to aortic valve sparing operations [3, 4]. I coined this name to differentiate these operations from aortic valve repair because one or more aortic sinuses were replaced at the time of aortic valve reconstruction. Here again the innovation was evolutionary. Our first aortic valve sparing operation was in a patient with acute type aortic dissection and a dissected and torn non-coronary aortic sinus. I reconstructed the aortic root by replacing the damaged non-coronary aortic sinus and ascending aorta with adjustment of the diameter of the sinotubular junction. That patient had a satisfactorily functioning aortic valve for 17 years when he developed an aortic root abscess and was successfully reoperated with replacement of the aortic root with an aortic valve homograft. My next aortic valve sparing consisted in replacing all 3 aortic sinuses with an intraoperatively tailored tubular Dacron graft. We were not aware that Sir Magdi Yacoub had performed such an operation before because his first peer-reviewed publication was printed in 1993 [5]. In 1989 we had our first intraoperative failure of remodeling of the aortic root and the patient required aortic valve replacement. We were troubled by the failure and careful examination of the intraoperative echocardiographic images suggested that the persistent aortic insufficiency was due to a dilated aortic annulus. I immediately turned my attention to aortic annulus. A few weeks later a new type of aortic valve sparing operation was born, the reimplantation of the aortic valve [6]. Here again, it was an evolutionary procedure. This new type of aortic valve sparing was developed to correct the dilated aortic annulus and sinotubular junction but it eliminated the aortic sinuses and placed the valve into a rigid cylindrical structure [3]. Next innovation in aortic valve sparing operations was an attempt to address the above issue and we modified the remodeling procedure

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by adding an aortic annuloplasty along the fibrous component of the left ventricular outflow tract to correct annular dilation [7]. The original work by Bellhouse and Bellhouse in 1968 described the important role that the aortic sinuses played on the closure of the aortic valve [8]. Other investigators found that the velocity of opening and closure of the aortic valve could be reduced by recreating the aortic sinus during the reimplantation procedure [9, 10]. We began to use a graft larger than needed for the reimplantation of the aortic valve and placed plicating sutures in end of the graft in the spaces that would correspond to the center of the nadir of the aortic annulus and in between commissures at the level of the sinotubular junction, as an attempt to create neo-aortic sinuses. D. Craig Miller visited us several times and observed the evolution of these operations and published a review article in 2003 where he listed these procedures as David I through V. David I was the reimplantation of the aortic valve into a straight tubular Dacron graft, David II the remodeling of the aortic root, David III remodeling with an annuloplasty, David-IV reimplantation with darts placed in the graft at the level of the sinotubular junction, and David V reimplantation with darts placed in the graft immediately below the nadir of the aortic annulus and in the spaces in between commissure at the sinotubular junction [11].

Mano Thubrikar and colleagues [12] conceived an expansible neo-aortic sinus by suturing 3 segments of corrugated Dacron fabric transversally at the end of a tubular graft, and patented this aortic root graft in the United States of America (patent #6544285). This modified graft was used clinically in a few patients [13]. Ruggero de Paulis and associates [14] developed what is now known as Valsalva Graft (Vascutek Ltd., Inchinnan, United Kingdom). The Cardio root Graft (Atrium Medical Corporation, Hudson, New Hampshire) has the same design as the Valsalva Graft, that is, the sinuses are spherical, which is anatomically incorrect as far as I am concerned. The normal aortic root evolves inside a cylinder and contains 3 bulges, the aortic sinuses. The aortic annulus is scalloped and attached to the aortic root along a single horizontal plan, and the only geometric shape that can provide this arrangement is a cylinder. If the aortic valve is reimplanted correctly inside the Valsalva Graft, the annulus will be distorted from its horizontal plane to a curve-linear one. This deformation of the annulus may adversely affect the durability of the aortic cusps. In other words, what is gained by adding aortic sinuses to the reimplantation procedure may be lost in durability because of deformation of the aortic annulus. Hans Sievers' group has designed and used an anatomically correct graft for reimplantation of the aortic valve which is now commercially available in Europe (Uni-Graft W SINUS, Braun, Melsungen, Germany) [15, 16]. A recently published study by Sievers' group on

4-dimensional cardiac magnetic resonance imaging of patients who had reimplantation of the aortic valve into the Uni-Graft showed fairly normal flows, with nearly physiological sinus vortex formation and transvalvular pressure gradients [17]. At the time of this writing there was limited clinical data on this graft. Hopefully its shape and size will not change with time as is common in ascending aortic grafts, [18] and it may prove to be the ideal conduit to reimplant the aortic valve in patients with aortic root aneurysm.

Clinical outcomes

We have carefully monitored our patients who had this operation since 1989 and reported the outcomes periodically. In our most recent publication [19] we described the outcomes of 333 consecutive patients with aortic root aneurysm who were treated with the reimplantation of the aortic valve from 1989 to 2012 and followed for a mean of 10.3 years (range 3–25 years). Our patients are relatively young (mean age 46 years and 35% younger than 40 years of age), and 133 had associated Marfan or Loeys–Dietz syndromes. Only 11 patients developed moderate or severe aortic insufficiency. At the end of 15 years we had 39 patients at risk and freedom from moderate or severe aortic insufficiency was $92.3 \pm 2.8\%$. Given that a change in the degree of aortic insufficiency can be captured only at the time of echocardiography, the precise time that the aortic insufficiency started cannot be determined by this type of study. For this reason, we treated time to develop aortic insufficiency as an interval-censored outcome. We used serial echocardiography data to create a longitudinal ordinal logistic regression model to determine the progression of aortic insufficiency over time. Time since initial operation was modeled as a third-order polynomial function, and an autoregressive covariance structure was used to adjust for the correlation between the multiple echocardiograms available for each patient. The result of this type of analysis is illustrated in Fig. 1. Six patients underwent reoperation on the aortic valve between 2 days and 25 years after surgery, including 1 for endocarditis and 5 for aortic insufficiency. Freedom from reoperation in the aortic valve was $96.9 \pm 1.3\%$ at 15 year with 39 patients at risk.

In a separate report [20] we described our experience with patients with Marfan syndrome and the overall results are even better than the entire cohort, likely because they were younger at the time of surgery. Reimplantation of the aortic valve has made a positive change in the lives of these patients which enhanced their lifespan and quality of life. An unresolved problem in this group is a persistent risk of aortic dissection of the remaining aorta after aortic valve sparing [20].

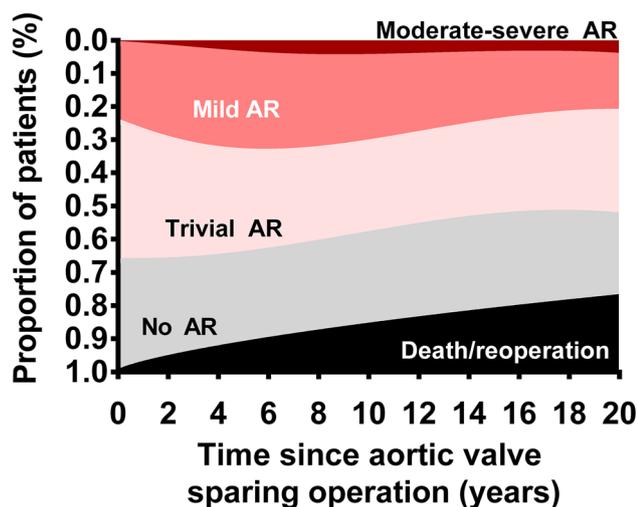


Fig. 1 Aortic insufficiency over time after reimplantation of the aortic valve (reproduced from David TE et al. *J Thorac Cardiovasc Surg* 2017;153:232–238 with permission)

Comments

The recurrent question is whether David procedure is superior to the classical Bentall operation to treat patients with aortic root aneurysm and if it is worth the risk of failure. A recent study from Johns Hopkins Hospital [21] compared the late outcomes of aortic valves sparing operations (69 patients with reimplantation of the aortic valve and 29 with remodeling) with Bentall (67 patients) and found equivalent results in terms of survival, risk of reoperation, and endocarditis, but fewer thromboembolic and hemorrhagic events. We recently conducted a similar study and used propensity score analysis to compare the late results of aortic valve sparing operations with aortic root replacement with mechanical and biological or bioprosthetic valves [22]. We found similar in-hospital mortality and stroke rate, but patients who had aortic valve sparing operations had lower rates of adverse valve-related events compared to the two other groups. In addition, the biological and bioprosthetic roots had increased risk of reoperation and mechanical valve group has increased risk of bleeding. Overall survival and freedom from cardiac deaths were better after aortic valve sparing but there were too many confounding factors to compensate for the differences among groups. Only a randomized clinical trial could address the issue of survival benefit and this is not a likely to be ever conducted because surgeons who believe in these operations will not randomize their patients and less experienced surgeons are not likely to provide the same clinical outcomes in the valve sparing group. Unlike the Bentall procedure that is relatively simple to perform and it is reproducible by most aortic surgeons, aortic valve

sparing, particularly the David procedure, is a complex operation that alters all components of the aortic root, that is, aortic annulus, aortic cusps, aortic sinuses and sinotubular junction and requires considerable experience to be done correctly. Kari and colleagues [23] examined the problem of residual and progressive aortic insufficiency in a large cohort of 764 patients who had aortic valve sparing in 3 cardiac units in Germany. Residual aortic insufficiency was present in 29% of patients and progressive aortic insufficiency was detected in 30% after a mean follow-up of 4.3 years [23]. The authors concluded that residual and progressive aortic insufficiencies are considerable after aortic valve sparing operations. My interpretation of that data is that aortic valve sparing operations are not easily reproducible and like mitral valve repair it should be performed only by surgeons with adequate volume and experience.

A few years ago, Prakash Punjabi from London, England, invited me to give a talk at a postgraduate course sponsored by the EACTS and he aptly titled my lecture as “The David operation—a success story”. Indeed, it has been a successful story in our cardiac center. As physiologically unsound as it may be, the clinical outcomes of reimplantation of the aortic valve into a tubular Dacron graft have been nothing short of outstanding when the operation is correctly performed in patients with normal or near normal aortic cusps [19]. Since our patients are relatively young, their aortic cusps may have adaptive mechanisms to function in a rigid structure without aortic sinuses, or it is also possible that the change in geometry of the reconstructed root with a smaller aortic annulus and larger sinotubular junction may provide a satisfactory condition for the aortic cusps to fulfill their function in spite of grossly abnormal flow as assessed by 4-dimensional cardiac magnetic resonance imaging [24].

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