

Transcatheter Aortic Valve Implantation

Clinical, Interventional
and Surgical Perspectives

Arturo Giordano
Giuseppe Biondi-Zoccai
Giacomo Frati
Editors

 Springer

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To Salvatore and Celestina, my awesome parents

– A. Giordano

To Gianni, my father

– G. Biondi-Zoccai

To Greta, my love

– G. Frati

Foreword

The subspecialty of interventional cardiology was born out of the clinical need for lesser invasive approaches to serious cardiovascular disorders, initially coronary artery disease. The evolution of this subspecialty has been fostered by the relentless drive to recognize and overcome obstacles, propelled by creativity and ingenuity. This pattern is clearly evident in the progression from balloon angioplasty to bare metal stents to several generations of drug-eluting stents, aided by advances in intravascular imaging, physiologic lesion assessment, and adjunct pharmacotherapy. These developments over the last 4 decades have led to increasing success rates, reduced complications, and greater durability of outcomes such that percutaneous coronary intervention has become by far the most widely utilized revascularization modality for patients with coronary atherosclerosis and has been demonstrated to save lives and improve quality of life for millions of patients around the world.

As the subspecialty of coronary intervention matured, the spark of invention spread to other applications, most extraordinarily to the treatment of patients with severe aortic stenosis. Aortic stenosis is a “simple” but debilitating disease that affects 5% or more of elderly patients, robbing quality and years of life. Aortic stenosis is becoming an increasingly important societal issue given the aging of the general population. And 1–2% of younger patients have a congenitally bicuspid valve, which prematurely can fail. Fortunately, surgical aortic valve replacement (SAVR) is an excellent operation that is successful in most. However, SAVR is still a major surgery, and as such carries substantial perioperative risks and morbidity. Some patients are too high risk to undergo SAVR, while others would prefer a less invasive option, with fewer complications and faster recovery.

Transcatheter aortic valve implantation (TAVI, as it is most commonly called in Europe), also known as transcatheter aortic valve replacement (TAVR, the term more widely used in the USA), was born out of this clinical need. In hindsight a brilliant but simple concept, the TAVI device at its core consists of a stent frame with a bioprosthetic valve contained within. Delivered most commonly through femoral access, the crimped stent valve is typically passed retrogradely across the stenotic aortic valve and then either via balloon expansion or self-expanding properties is implanted in the aortic annulus, excluding the native diseased valve. The first procedure was performed by Alain Cribier in Rouen, France, on April 16th, 2002, in an inoperable and

desperately ill 57-year-old man in refractory cardiogenic shock due to critical calcific aortic stenosis. The procedure was successful, igniting extraordinary enthusiasm, accelerated development efforts, and subsequent proof of clinical safety and efficacy of a new procedure to a degree heretofore not previously seen in medicine.

Initially TAVI was applied to very elderly patients at prohibitive surgical risk with severe aortic stenosis. A large-scale randomized trial demonstrated that a balloon-expandable device markedly improved quality of life and reduced mortality, with one life saved for every five patients treated—an almost unheard of magnitude of benefit. Similar outcomes were demonstrated with a self-expanding TAVI device in a similar patient population in a non-randomized study. TAVI with both balloon-expandable and self-expanding versions was subsequently shown in large randomized trials to have similar or even slightly higher rates of survival compared with SAVR in high-risk surgically eligible patients with severe aortic stenosis. But high complication rates with these early generation devices were evident, especially bleeding and vascular events, among others, and in some studies stroke tended to be more common than with surgery. In addition, severe peripheral vascular disease in some patients necessitated TAVI introduction through a transapical myocardial approach in some patients, a less desirable route fraught with more frequent complications.

Consistent with the history of interventional cardiology, once these issues were recognized they were addressed by improved technology and technique. Lower profile devices were developed translating to less bleeding and adverse vascular events, and fewer patients requiring transapical access. Paravalvular leaks in some devices were reduced by the addition of an external sealing cuff. An excessive rate of pacemakers with other devices was lowered with an optimal technique. Improved vascular closure approaches were developed. And so forth.

With these improvements large-scale randomized trials were progressively performed with each class of device first in intermediate-risk patients and then low-risk patients with severe aortic stenosis, demonstrating first comparable outcomes but most recently improved survival free from stroke and hospitalization compared with SAVR. Indeed, the rapidity with which a massive amount of high-quality randomized trial evidence was generated to support the safety and efficacy of these devices is unparalleled in the annals of medicine. And more is on the way, with ongoing studies in bicuspid aortic stenosis in younger patients, asymptomatic patients with severe aortic stenosis, moderate aortic stenosis with heart failure, predominant aortic regurgitation, treatment of failed surgically implanted valves and rings, and implants in diseased native mitral valves with heavy annular calcification. Additional studies are addressing the optimal periprocedural and long-term pharmacotherapy to prevent leaflet thrombosis after TAVI while minimizing bleeding. Novel approaches have been developed to prevent cerebral embolization, and avert or treat rare but serious complications such as coronary obstruction and aortic rupture. Large-bore closure devices have been introduced which promise to further reduce vascular complications and shorten time to ambulation and discharge. Dozens of novel TAVI designs have been developed to allow

the device to be more easily repositioned or recaptured, to enhance tissue biocompatibility and longevity, treat patients with aortic insufficiency and dilated aortic roots, and further enhance the reproducibility and safety of the procedure.

An undeniable success story, the development, evolution, practice, and future of TAVI deserve documentation in a major textbook. In this regard *Transcatheter Aortic Valve Implantation: Clinical, Interventional and Surgical Perspectives*, edited by Arturo Giordano, Giuseppe Biondi-Zoccai, and Giacomo Frati, is an incredible effort in which the pathophysiology of aortic valve disease, diagnosis of severe aortic stenosis and patient selection for TAVI, alternative TAVI devices, techniques, outcomes, and adjunct technologies are thoroughly reviewed. The role of the heart team is emphasized, with the preferences of the informed patient at the center of clinical decision-making. The 48 chapters in this book contributed by more than 100 authors comprehensively describe the past, present, and future of this astonishing journey.

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Preface

The beginning is the most important part of the work

Plato

Cardiovascular disease represents one of the major causes of mortality, morbidity and resource use worldwide [1]. Rosy declines in the incidence of cardiovascular death in high-income countries have been partly offset by increased incidence and prevalence of several cardiovascular conditions in other countries, and a shift from coronary artery disease to other conditions. Accordingly, and also thanks to an overall increase in life expectancy, clinicians have seen an overall increase in the prevalence and burden of degenerative aortic valve stenosis [2, 3].

Such booming need for appropriate management of aortic valve disease poses several challenges [4]. First, the role of prevention and medical therapy is still very limited, if present at all, thus restricting the opportunity for simple, cheap, and large-scale approaches [5]. Second, aortic valve disease in general and degenerative aortic valve stenosis in particular often occur in elderly subjects fraught with major comorbidities, which heavily impact on treatment choices and subsequent management [6]. Third, surgical aortic valve replacement with a mechanical or biologic prosthesis has remained until recently the gold standard treatment for severe aortic disease in fit patients [7]. However, it represents major surgery requiring cardiopulmonary arrest and extracorporeal circulation, with substantial risk and cost implications.

Thanks to the pioneering efforts of Gruentzig, Labadibi and Cribier [8–10], among many others, severe aortic valve stenosis can now be managed with a minimally invasive technique: transcatheter aortic valve implantation (TAVI), also called transcatheter aortic valve replacement (TAVR). Despite its junior age, transcatheter aortic valve implantation has already managed to reach and overcome several important milestones. Indeed, devices have evolved dramatically from first-generation to more refined ones [11]. Accompanying clinical evidence has been accrued spanning from randomized trials to observational studies and case series, supporting the adoption of this technology in several settings, including prohibitive risk patients, intermediate risk patients, failed bioprostheses, highly selected cases of aortic regurgitation, and, most recently, low-risk subjects [12–15]. But the greatest driver of transcatheter aortic valve implantation successes is surely the team effort which has been sought from the beginning by all researchers, practitioners, and stakeholders involved. Indeed, transcatheter aortic valve

implantation has proved as a landmark example of heart team involvement in device development, patient selection, procedural strategy, and subsequent management [16].

Several good books have been compiled on the topic of transcatheter aortic valve implantation or transcatheter valve repair at large, including the recent concise manual by Watkins et al. [17], as well as the leading textbooks by Ailawadi and Kron [18], and Tamburino et al. [19]. Yet, no work to date has explicitly aimed at capitalizing the successes of the heart team approach in the design and leadership of an authoritative textbook devoted to transcatheter aortic valve implantation.

Our aim was explicitly this. The editor team comprises a leading interventional cardiologist with hands-on transcatheter aortic valve implantation, an expert clinical cardiologist with established track record in evidence synthesis and non-structural cardiac interventions, and a pioneering cardiac surgeons with expertise in valve repair as well as translational research. Accordingly, chapters have been provided by leading clinicians, invasive cardiologists, and surgeons, with the shared belief that different perspectives may be integrated in a constructive fashion through the heart team approach, for the ultimate benefit of patients as well as everybody involved in their care.

More precisely, this textbook has been divided in five main sections. The first part of the work deals with the pathophysiology of aortic valve disease and most promising translational perspectives, including the role of inflammation and key hemodynamic issues. The second section focusing on clinical aspects of direct relevance for patient selection. Specifically, risk scores, imaging modalities, concomitant coronary artery disease, gender differences and implementation issues are all systematically analyzed. The third part includes chapters with an obvious interventional focus, including several chapters dedicated to the various available devices, individualized device choice, as well as ancillary management including antithrombotic therapy and renal protection. The fourth section maintains a direct surgical perspective, emphasizing the role of the heart team, use of alternative accesses, and hybrid procedures. The last part of the textbook provides more thought-provoking contributions, for instance on medical therapy, pure aortic regurgitation, and bioresorbable valves.

In conclusion, we are confident that this comprehensive book on transcatheter aortic valve implantation will prove useful to clinicians, interventionists and surgeons by providing a plethora of important pieces of information, while emphasizing the need for heart team involvement and shared decision-making.

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Acknowledgments

The common eye sees only the outside of things, and judges by that, but the seeing eye pierces through and reads the heart and soul

Mark Twain

When I try to think about the people who contributed to the realization of my professional life, I cannot really stop adding up names to the thank you list.

After a while, though, a clear sequence bumps into my mind. Indeed, at the first and foremost place, there is my family. Fiammetta, my wife, who is a passionate medical researcher, helped me discover my passions. She supported me in all the difficult moments and stimulated me culturally everyday. Furthermore, she owns the merit of raising our wonderful children: Celeste, Carolina and Salvatore, who are lovely and sympathetic, and have always been a strong motivation for me. My siblings. Then there is the person who introduced me to the world of invasive cardiology: Professor Carlo Vigorito. He was a true teacher and a distinguished connoisseur of cardiovascular physiopathology. I am infinitely grateful to him. Among his students, Paolo Ferraro, who has always been my partner in the catheterization laboratory. We spent all our professional careers side by side, thanks to his technical skills and human virtues, especially his patience. A great boost to our activity, for sure, began with Nicola Corcione. He is a great clinical cardiologist and an extraordinary interventional cardiologist, and indeed the catheterization laboratory is his natural habitat. Furthermore, Giuseppe Biondi-Zoccai highly contributed to the scientific aspects and elaboration of all the work that we have done. I must thank as well our lifetime cath lab collaborators, Pasquale and Riccardo, who have always been crucial to ensure the safety of our patients and the success of our procedures, as well as our secretaries Stefania, Eleonora and Raffaella, for constantly organizing our job and the latter for managing the scientific activities. A special thank goes to Vincenzo Schiavone, his wife Annamaria and his son Beniamino, who lead Pineta Grande Hospital and who believed in our job and supported, with great foresight, the structural interventional cardiology program.

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Castel Volturno, Italy
April 25, 2019

Arturo Giordano

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Latina, Italy
April 25, 2019

Giuseppe Biondi-Zoccai

I am proud to dedicate this textbook to the greatest love of my life, my daughter Greta.

Greta, you are the gift of my life.

This book is also dedicated to Giorgia, the love of my life, the mother of my princess.

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Latina, Italy
April 25, 2019

Giacomo Frati

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