EDITORIAL

Transcatheter aortic valve replacement: A breakthrough medical therapy! The 20-year odyssey, and now, a 10-year anniversary

Remplacement valvulaire aortique percutané: un traitement médical révolutionnaire! Une Odysée s’étalant sur 20 ans et maintenant le 10e anniversaire

The concluding statement from a first-in-man case report published in Circulation in 2002 was: “Nonsurgical implantation of a prosthetic heart valve can be successfully achieved with immediate and midterm hemodynamic and clinical improvement” [1]. The lead author of this short manuscript was Alain Cribier, and the procedure involved transcatheter placement of a bioprosthetic aortic valve in a desperately ill man with critical aortic stenosis (AS) and no therapy alternatives. At the time, it was impossible to predict the future of this new medical therapy, which at the same time appeared both reckless and revolutionary. In retrospect, 10 years later, this humble concluding statement laid the foundation for a medical breakthrough that has altered the landscape of cardiovascular medicine. The odyssey and the anniversary of transcatheter aortic valve replacement (TAVR) deserve our attention and careful reflection.

To qualify as an important medical breakthrough, a new therapy must fulfil five criteria:

- address an important unmet clinical need for a common disease;
- apply innovative technology solutions that are disruptive in nature;
- have validated incremental therapy benefit via rigorous evidence-based medicine standards;
- can be generalized to the practising medical community at large;
- stimulate change in the milieu and pattern of medical practice beyond the narrow confines of the procedure itself.

There is little doubt that TAVR, as currently practised around the world, addresses an unmet clinical need for a common disease. The prevalence of AS in people over the age of 75 years is approximately 5%, and with a rising aging population, the optimal treatment of calcific AS is becoming an important global healthcare concern. Over the past decade, the medical community has finally acknowledged that AS in the elderly, especially in patients with threatening co-existing illnesses, is both under-diagnosed and under-treated. At least one-third of patients with severe AS and cardiac symptoms do not currently undergo conventional surgical aortic valve replacement [2,3]. This is not merely a resource allocation issue affecting certain geographies, but rather a general concern in all clinical practice environments in all parts of the world. Simply stated, less-invasive treatment strategies are necessary to successfully treat elderly AS patients with significant co-morbidities.

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As an innovative medical technology, TAVR is among a handful of medical therapies to emerge in the past decade that promise to fundamentally change treatment practice. The mere concept that a diseased native aortic valve can be replaced and functionally transplanted with a new bioprosthetic valve using solely percutaneous techniques strains the imagination of even the most creative thinkers. Yet, the essential components of TAVR are largely iterative and derive from predicate advances in surgery and interventional cardiology. The vision of a valve on a catheter was introduced more than 50 years ago by Davies [4] and was later refined by Andersen et al. in seminal animal investigations [5]. Mechanical dilatation of stenosed aortic valves was pioneered by Cribier and his colleagues in 1986 [6] but was soon discarded due to early complications and frequent recurrences. Soon thereafter, improved durability of bioprosthetic surgical valves and the emergence of permanent metallic vascular scaffolds (endovascular prostheses or “sten”) offered new possibilities. Nevertheless, these fundamental components required creative integration into prototype devices. The final products were a remarkable technology achievement — catheter-based balloon-expandable (or self-expanding) support frames attached to and incorporating bioprosthetic valves, which could be delivered and released remotely and predictably to target sites in a beating heart. Still, these technology marvels required the creative genius and persistence of first Bonhoeffer et al. in 2000 [7] and then Cribier et al. in 2002 [1] to bring such devices into the clinical arena. TAVR truly qualifies as a “‘disruptive’ technology, in that a different view proposition for AS therapy was introduced, which is faster, simpler and more generally applicable to patients around the world.

The acceptance of TAVR as a legitimate medical therapy demanded careful evidence-based medicine validation. A radical (and expensive) technology applied in elderly comorbid patients naturally evoked controversy, scepticism and overt criticism. Early clinical trials in this field were self-reported single or multi-institutional reports, which were at once both clarifying and confusing. In defence of these initial clinical research efforts, it was problematic to subject a rapidly evolving technology and procedure to overly aggressive research scrutiny. Within several years, stabilization of the TAVR platforms and improved research methodologies [8] led to the development of carefully conducted clinical trials in appropriate patient subsets [9,10]. The Placement of Aortic Transcatheter Valves (PARTNER) randomized trials [9,10] definitively established TAVR as a new standard-of-care in severe AS patients without surgical options and as an alternative to surgery in high-risk patients. This commitment to the highest principles of evidence-based medicine is imbued in innumerable ongoing international TAVR research programmes and should become a vital guidepost as TAVR is carefully and appropriately integrated into clinical practice.

Since the introduction of TAVR to the European community in 2007, there has been a dramatic 40% compound annual growth rate, such that by the end of 2011 almost 20% of all aortic valve replacement procedures in some large European countries were performed via transcatheter methods. Careful physician and site training programmes have been developed, incorporating didactic sessions, medical simulation techniques, case presentations and on-site proctoring to ensure the disciplined dispersion of this formidable new technology. Thus far, employing these training algorithms, almost 50,000 TAVR procedures have been performed in more than 500 clinical centres around the world. Concerns regarding the possibility of deteriorating outcomes, downward ”risk drift” in less well-defined patient subgroups, and overly enthusiastic expansion to less qualified centres are being carefully scrutinized by societies and government agencies [11].

Perhaps the most important contribution of TAVR to the advancement of medicine is not the technology or the clinical outcomes, but rather a unique culture that has arisen. The territorial practice of subspecialty medicine has been replaced by a disease-state model requiring multidisciplinary physician collaboration. The ”Heart Valve Team” approach to TAVR practice has joined surgical, interventional and imaging specialists in the best interest of patient care. This multidisciplinary group dynamic stimulated by TAVR will dissolve previous barriers and likely foster a constructive change in future practice patterns in other subspecialties. Even the procedural milieu is being modified — a shared so-called ”hybrid” environment, which allows the seamless integration of interventional and surgical therapies. This integration also encompasses a multimodality imaging approach to assist with diagnosis, case planning and intraprocedural decision-making. Thus, TAVR by virtue of its complexity and novelty has challenged the foundations of medical practice, and ”won”. We are now a physician community combining advanced skill sets in the most advantageous treatment environments, resulting in the achievement of synergistic clinical outcomes.

By all criteria, TAVR is clearly a ”breakthrough technology” and medicine owes a great debt to the passionate and humble pioneer, Alain Cribier, whose relentless pursuit of a dream culminated in a life-saving reality. This special edition of Archives of Cardiovascular Diseases celebrates Cribier’s ”triumph of the human spirit” — his pilgrimage to shepherd TAVR from a prototype device concept, through years of animal experiments, to the early courageous clinical cases, which were both exhilarating and agonizing, to current refinements in technology and procedures that have resulted in an extraordinary medical advance. His friends and colleagues, many now important thought-leaders, have shared their expertise to craft a special celebratory issue in his honour. The introductory manuscript, authored by Cribier himself, is a historical tour of the 20-year odyssey highlighted by many personal reflections. This is followed by a detailed account from a cherished colleague, Helene Etchaninoff, describing clinical results in Rouen, comparing previous and new transfemoral TAVR systems. John Webb, equal parts disciple and pioneer, provides a technology tour-de-force of evolutionary changes in devices, delivery systems and access routes. The future vision of TAVR — simpler and safer — that is, better devices and fewer complications, is articulated by a European leader in valvular heart disease, Alec Vahanian. Surgical perspectives and a review of transapical TAVR experiences are thoughtfully discussed by Thomas Walther and Pierre-Yves Litzler. Finally, in a tribute to the ”next generation” of interventional scientists, the topics of United States TAVR experiences, patient selection and biomedical engineering perspectives are reviewed by accomplished junior academicians.
The 10-year anniversary of the first TAVR implant in Rouen, France, by Alain Cribier and his team represents a landmark event in the history of medicine. During a featured lecture at the Transcatheter Cardiovascular Therapeutics symposium in 2011 in San Francisco, Alain Cribier quoted Andre Gide as follows: "One doesn’t discover new lands without consenting to lose sight of the shore for a very long time". At this momentous occasion, all of medicine would agree that Alain Cribier has discovered new lands with an indomitable spirit and a special vision that gazes across oceans — in the noble pursuit of satisfying his passion for helping patients.

Disclosure of interest

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References


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