The Heart Team, TAVI and natural selection

“The slow one now will later be fast... for the times they are a-changin” - Bob Dylan

The announcement in 2002 that Alan Cribier had performed the first Transcatheter Aortic Valve Implantation (TAVI) ranked right up there with the announcement that the first heart transplant had been performed by Chris Barnard, or the announcement that Andreas Gruentzig had performed the first coronary angioplasty. At the time we rightly viewed this as an exciting breakthrough in the management of patients with aortic stenosis and had little reason to anticipate that perhaps the major challenge for TAVI still lay ahead. We now know that we can replace the aortic valve via a percutaneous technique. We also know that we can achieve comparable results to surgical aortic valve replacement with this percutaneous technique. To prove this we have primarily applied the technique to the elderly, high risk surgical candidates, often considered inoperable. In doing so we have prolonged the lifespan and/or improved the quality of life of a number of patients. However, in a fair number of patients we have achieved neither a longer life, nor a better quality of life. The challenge to select the patient who will benefit from a TAVI may be more difficult to achieve than the technical challenge of performing this amazing procedure.

The innovation of TAVI has empowered us with the ability to successfully treat advanced aortic stenosis in patients of advanced age, often with advanced co-morbidities. However, the sobering reality is that a substantial portion of these patients will not benefit from this procedure. The challenge that we have not yet mastered is to select the patient who will benefit from the procedure whilst advising against the procedure in patients who will not benefit, thus avoiding futility and potential harm.

This issue of SA Heart features an important consensus statement by the South African Cardiovascular Society of Cardiovascular Intervention (SASCI) and the Society of Cardiothoracic Surgeons of South African (SCTSSA), providing guidance for practitioners performing TAVI. They address the establishment of a TAVI team, the requirements of the Multidisciplinary Heart Team (MDT) and they also list the indications and contra-indications for TAVI. The section dealing with patient selection is, perhaps understandably, glossed over, stating only that the requirements are: a.) proof of severe symptomatic aortic valve stenosis and b.) patient evaluation by a MDT. It is the latter recommendation that is fraught with difficulty. One of the contra-indications for TAVI listed in the consensus statement is a predicted life expectancy of less than a year. A very logical recommendation that most of us would argue is medically, morally and
ethically sound. Consider now the 1-year outcome data report for patients in the CoreValve US Pivotal Extreme and High Risk trials. Thirty percent were dead at 1 year. If one knew that up-front, TAVI would have been contra-indicated in a third of these patients. Add to that the fact that fifty percent of the patients in these trials had a poor outcome (defined as death, a poor quality of life or a worsening of quality of life compared to the pre-TAVI status), one can only wonder what patients would say if they are told, when providing informed consent, that a favourable outcome at 1 year could best be predicted by flipping a coin. Of course one must immediately take cognisance of the fact that these results were achieved in a geriatric population (average age 83.3 years) considered to be at high risk or extreme risk. The future of this procedure may well involve younger patients at significantly lower risk. However, the fact remains that while we can perform a TAVI in very old patients at very high risk, we have yet to master the challenge of selecting the right patient to ensure that we do not cross the line that would lead to futility.

The dilemma that the MDT face when evaluating a patient being considered for a TAVI is that the very reasons giving rise to the patient not being considered for surgical aortic valve replacement (such as advanced lung disease, advanced renal disease, advanced age and frailty) are also the best predictors of a poor outcome with TAVI. Recent publications are indicating the direction we have to take to select patients appropriately for TAVI. Clearly the decision must be taken by a MDT. The MDT must include sufficient expertise beyond the opinion of the cardiac surgeon and cardiologist involved in the procedure. Recommendations are that the MDT should include the primary or treating cardiologist, the interventional cardiologist, the cardiac surgeon, the anaesthesiologist, imaging specialists, rehabilitation specialists, advanced care nurses, social workers and administrators. The decision must be based on a number of indicators, in addition to the standard surgical risk indicators, such as the Society of Thoracic Surgeons (STS) mortality risk score including lung function, renal function, age, indicators of frailty (such as inactivity and unexplained weight loss) and indicators of disability or inability to perform activities of daily living (such as dressing and feeding independently). Studies suggest that it is not necessary to perform cumbersome or complex tests such as grip strength or walk speed although specific tests such as a 6 minute walk test as an indicator of functional impairment, or a serum albumin as an indicator of catabolism or malnutrition, may improve the accuracy of predicting.

Incredible developments in treating advanced cardiac disease are being added to the armamentarium of the cardiologist at an impressive rate. Device therapy allows us to prevent a bradycardic death by implanting a pacemaker, to prevent a tachycardic death by implanting a defibrillator, to prevent a
haemodynamic death by implanting an aortic valve without surgery. We can improve the outcome and the quality of life of selected patients with end-stage heart failure with a cardiac resynchronisation therapy (CRT) device. The word “selected” is perhaps the key word here. Many of the conditions and devices listed are being used to treat patients with advanced pathology, often of a degenerative and progressive nature. The ability to prolong life and to improve the quality of life is a finite one. The next leap in our ability to treat patients with cardiovascular disease may not be another wonderful device, but rather the ability to accurately select patients who will, or will not, benefit from a particular therapeutic option.

When Bob Dylan sang “The slow one now will later be fast” he was not necessarily referring to very old patients with advanced cardiac disease. However, he may well have had our profession in mind when he sang “for the times they are a-changin’.

REFERENCES