Shifting Paradigms and Financing a Revolution: Providing Transcatheter Valves in the Public Health System. A View from Aotearoa New Zealand

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In *The Structure of Scientific Revolutions*, Thomas Kuhn, the American philosopher of science, argued that scientific advances occur by revolution when the dominant scientific theory of the day is lacking and is rapidly replaced by a new radical theory.[1] For example, the European voyages to the Americas in the 15th and 16th centuries required accurate navigation. The prevalent geocentric view at the time, that the celestial bodies circled the Earth, was woefully inaccurate as a basis for transatlantic navigation. Accordingly, the geocentric view was overthrown and rapidly superseded by the heliocentric view put forward by Copernicus, which provided much more accurate navigation. There was, to use Kuhn's terminology, a paradigm shift. As with all revolutions, there were casualties. The imprisonment of Galileo is well known, but Michael Servetus (who is credited with describing pulmonary circulation before William Harvey) was burned at the stake under Calvin's orders, partly for embracing this idea. The recent trials in transcatheter aortic valve implantation (TAVI) have resulted in a paradigm shift away from surgical aortic valve replacement (sAVR) as the gold standard definitive therapy in the treatment of aortic stenosis.[2–8] It seems that a revolution is underway in the treatment of aortic stenosis, but hopefully without imprisonments or burnings.

Background

Aortic stenosis is a common condition affecting about 4–5% of the population aged 65 years.[9] sAVR has traditionally been the mainstay of treatment, but over the past decade, a number of landmark studies have demonstrated that TAVI is a viable alternative.[2–8] Such is the rapidity at which new information is becoming available, guidelines become outdated almost as soon as they are written. The mounting data are compelling, TAVI is at least as effective as sAVR in treating aortic stenosis, and quite likely superior in the short term.[2–8]

Minor concerns exist around the increased requirement for permanent pacing and subsequent coronary access if coronary disease supervenes, particularly if younger patients are to be treated. Moreover, there are no long-term data about valve durability, but this must be balanced by a paucity of data on the durability of most surgical bioprostheses. Such is the appeal of TAVI amongst patients and their referrers, that even if transcatheter valves were ultimately shown to be less durable, it is likely that many patients would still prefer TAVI to avoid a thoracotomy and a longer recovery time.

New Zealand, like the UK, has a comprehensive taxation-funded health service, and like the British, New Zealanders are proud of the services it provides. In fact, the New Zealand system is older than the UK National Health Service. It was introduced in 1938 by the first New Zealand Labour government, who envisaged free healthcare for all. While there are subtle differences between the New Zealand Heath Service and the National Health Service, they share the same basic philosophy; that treatment is provided based on need and free at the point of delivery. In fact, universally free healthcare has never been totally achieved in New Zealand. GP visits, for example, are only partially funded and attract a co-payment from the patient.

The land mass of New Zealand is about the same as that of the UK. The population is considerably smaller, around 5 million. This population is geographically dispersed, and health is coordinated by 19 District Health Boards (DHBs), which are semi-autonomous. Interventional cardiology procedures are provided in 10 DHBs, whereas TAVI and cardiothoracic surgery are provided in five (Auckland, Waikato, Wellington, Christchurch and Dunedin). There are mature hub and spoke relationships between these tertiary centres and the populations of smaller towns.

The landmark randomised trials have advanced our understanding of who should receive TAVI to treat aortic stenosis. Given the fact that these trials were performed by high-volume operators in tertiary institutions, they also inform us where they should be performed and by whom.

The recently published British Cardiovascular Intervention Society Service Specification for TAVI is an important addition to the literature. It recommends that TAVI should take place in large tertiary centres with on-site cardiac surgery, interventional radiology, intensive treatment unit and

the like, so that in the rare case where a complication occurs, immediate help is available. In countries, such as the UK and New Zealand, that have public healthcare funding, this means the large tertiary public hospitals. These are the institutions that employ cardiologists with the required skills and provide enough suitable patients on which these skills can be maintained. There is an obvious benefit of coordinating TAVI through large publicly funded institutions.

Current Obstacles

Undoubtedly, public health systems do 'large' very well. However, there are notable downsides to the way large public hospitals operate, given the fact they are invariably resource constrained. Public systems are cumbersome and not agile enough to change funding streams at short notice, even when compelling evidence of an alternative emerges. In New Zealand, the public health system is struggling to adapt to a sudden change in treatment paradigm, as is dictated by the low-risk TAVI trials.[6–8] In New Zealand, budgets are set based on existing activity (i.e. current sAVR volume), and are allocated by service, rather than pathology. Any changes to this will take both time and skilful diplomacy. Theatre staff and surgeons are already employed on lifelong contracts, and it would be untenable to terminate their employment. It would be difficult to redeploy cardiac surgeons as TAVI interventionists without considerable and lengthy retraining. The skillsets of cardiologists and cardiac surgeons are markedly different. Cardiac surgeons will undoubtedly continue to be employed by public hospitals and be freed up to perform other procedures. It is ironic that the legacy of the landmark studies may result in faster surgery for patients with lung cancer, and longer waiting times for TAVI patients in public hospitals.

TAVI patients rarely require an intensive treatment unit bed, and have shorter hospital stays and fewer subsequent readmissions compared with patients undergoing sAVR. Accordingly, it has been shown in the US healthcare system that TAVI is cheaper than sAVR, despite the higher cost of the prosthesis.[10] It seems very likely that TAVI will be a cheaper option in publicly funded health systems too. On the face of it, a simple solution to facilitate an expansion in TAVI volumes would be to transfer funding from sAVR. However, as mentioned above, it may not be so simple to achieve this in publicly funded systems in the short term.

The reduced costs demonstrated by Baron et al. relate simply to the costs of the procedure and subsequent care.[10] They do not include new costs, such as those required to commission additional facilities and employ staff. Existing catheter laboratories in New Zealand are already stretched performing other interventional work. Wait times in our centre for elective coronary or electrophysiology procedures can be some months, and this is similar around the country. Even acute procedures are delayed, with the most recent data from the All New Zealand Acute Coronary Syndrome Quality Improvement Programme registry suggesting only 71% of those patients who have angiograms for non-ST segment elevation MI are performed within 72 hours (the maximum acceptable wait time recommended by the European Society of Cardiology guidelines).[11,12] This compares favourably with 57% in the UK, but quite poorly with 92% in the US, where resource constraint is less of an issue.[13,14] There is limited spare capacity in the public system to perform extra TAVIs. To increase volumes, extra catheter laboratories may need to be commissioned and trained structural interventionalists employed. Any funding would have to compete with other worthy treatments; for example, cancer and mental health.

The classic response of constrained systems is to rigidly cap volumes, and two of the DHBs offering TAVI in New Zealand have done this. In the other three, the decision to treat a patient with aortic stenosis with one modality rather than another is made by a multidisciplinary team in line with the British Cardiovascular Intervention Society service specification document. It may appear that these DHBs are enlightened, but without increased infrastructure, the waiting lists have grown in these centres. Currently, there is little hope that patients can receive TAVI within 18 weeks of referral, as recommended in the British Cardiovascular Intervention Society service specification document. Whereas previously, a person may have received timely sAVR, the increased time to wait for TAVI may offset any advantage shown by randomised trials. However, such is the success of TAVI that patients and referring cardiologists are reluctant to consider surgery.

There is a danger that hard-pressed DHBs will be forced to outsource TAVI volumes to smaller private institutions to reduce waiting times. Alternatively, the DHBs could insist that patients with aortic stenosis continue to be treated by sAVR. This will increase the cost of the treatment and may lead to a reduction in quality of outcomes.

Conclusion

TAVI is disruptive, dominant and revolutionary technology. It ameliorates aortic stenosis with better outcomes, at a lower cost and with more rapid recovery than sAVR. While it is not the panacea for all aortic valve ills, the recent evidence suggests that many patients who would have previously undergone sAVR for aortic stenosis could be treated with TAVI. It would be a shame if public systems could not offer it to suitable patients. Cardiologists can certainly advocate for more funding and transfer of resources. However, as a community, we should also look at our own practice and the other procedures that we perform. Do we need to be conducting so many percutaneous coronary interventions for patients with stable coronary disease or pulmonary vein isolations for AF?[15–17]

We must not lose sight of the fact that the most important part of this revolution is the person with aortic stenosis. Without major change in practice, or a windfall in funding, it is difficult to see how a publicly funded health system will cope with the increasing workload, and patients with this lethal condition will not receive the best treatment. In the short term, this might mean continuing sAVR for some low-risk patients, to avoid patients coming to harm by waiting on a long TAVI list. In the medium term, funding should be diverted from sAVR into TAVI programmes, with the aim that appropriate patients are given the best treatment according to the scientific studies. Careful consideration is required, and urgent dialogue necessary between clinicians, funders and providers to facilitate a peaceful revolution. Without this, there may be imprisonment and burnings at the stake. ❑

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