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Transcatheter aortic valve implantation (TAVI): how to interpret the data and what data is required?

Martyn Thomas, MD, FRCP[1]*; Olaf Wendler, MD, PhD, FRCS[2]

1. Guys and St Thomas' NHS Foundation Trust, London, United Kingdom; 2. King's College Hospital NHS Foundation Trust Denmark Hill, London, United Kingdom

When a new device is introduced into the cardiology world, evaluation of the outcomes is important, but vexed with problems. It is, however, a mutual responsibility of the physician and device sponsor to ensure that evaluations ensue at each stage of any technological evolution. Transcatheter aortic valve implantation (TAVI) is a new procedure with the first implant in man in 2002 and the start of commercial use in Europe in 2007. The technology is still in its infancy and there is much yet to learn. This editorial is a "Call to Arms", inviting industry and physicians to set a standard of clinical evaluations with the aim of harmonisation of endpoint definitions, fair and consistent reporting and earnest analysis of the trends in outcomes over time. Clinical trials for new device technology, like the procedures themselves, are an evolutionary process. There is a place and time for various methodologies, commencing with "first-in-man" studies, followed by controlled feasibility and, ideally, randomised controlled trials. Once "launched", the importance of ongoing surveillance through well managed prospective observational registries becomes critical, as the trends in data guide further development, clinical decision making and set guidelines for "real world" practice. The data also support economic evaluations and trends in the displacement of new procedures over old. In all phases of clinical evaluation, the data must be interpretable. Therefore, the method by which data is collected and reported, with this, and other new procedures is an important aspect of the roll-out of a new technique into a real world environment. Recent scientific position statements issued by EACTS/ESC[1], AHA[2] and STS[3] have paved the groundwork for trial and data considerations in this burgeoning field. By virtue of time to publication, the current data on TAVI reported in the literature reflects the historical learning curve of the transcatheter technique[4-10]. The demand for "late breaking" clinical data to inform all stakeholders regarding the progress and promise of a new technology often invites a rush to report in congresses incomplete and small data sets of observational experiences. There must be discipline in order to ensure that this mere "bean counting" is replaced by a more meaningful methodology and discussion of trends in outcomes over time. There are currently two commercial entrants in the TAVI field, Edwards Lifesciences and CoreValve, Inc. each with substantive clinical series totalling more than 5,000 patients treated. At this moment in the historical evolution of the field, more peer-reviewed manuscripts must be encouraged in addition to robust reporting of the observational registries. Publications drive clinical practice. Therefore, it is incumbent upon the physician leaders, with first access to the technology, to report results for implants in accordance with prospective registry programs offered by the companies.

Assuming that the registry data is collected in as honest and intellectually sound manner as possible, even if without robust methodology, the "real world" data will guide the evolution responsibly. Without such diligence and discipline, history has taught us that promising new technologies can be delayed or doomed.

The expression "learning curve" is frequently used with reference to early experiences with a new technology. However, it should be possible with TAVI procedures for the learning curve of start-up centres to be virtually eliminated with correct training and proctorship. The fact that the latest Edwards SAPIEN and CoreValve registry data are superior to the published data (despite many centres in the registries performing their first cases and the published literature coming from the most experienced centres in the world) reflects a number of factors. The technique has developed and early operators have been able to share their learning curve with the rest of the interventional and surgical community. This has included a switch from the antegrade to retrograde approach. The antegrade, transseptal approach, was a technically highly difficult procedure with numerous potential complications. The transfemoral, retrograde approach, is technically easier, but does imply the introduction of large French catheters into the arterial circulation. To overcome these potential peripheral complications and access issues, the transapical (Edwards) and subclavian (CoreValve) approaches have been developed. The equipment has improved substantially, including a reduction in Fr size with both platforms. Patient selection has improved and commercial "labels" have been refined to include better training content. Finally, minimum standards have developed for units wishing to carry out such procedures, including the development of multidisciplinary teams and min-

* *Corresponding author: Guys and St Thomas' NHS Foundation Trust, Lambeth Palace Rd, London SE1 7EH, United Kingdom*
E-mail: mttwins@aol.com

imum training requirements. These training requirements demand didactic lectures, simulators, observed cases and proctored cases. Current indications for the TAVI procedures include patients with symptomatic severe aortic stenosis in high risk surgical patients, generally those with a logistic EuroSCORE of >20 or an STS score of >10. The development of the technique will depend on the relative risks and benefits of the procedure. It is likely that the risk profile of the patients will gradually come down, but this should only happen as the procedure becomes more robust in terms of both short and long term outcomes. Again, it therefore becomes imperative that such trends are responsibly studied in prospective clinical trials and not via "risk creep" in unmonitored clinical practice. Registries will not replace the need for such trials, but should guide the hypotheses tested in these trials. It is important that these data are carefully collected in all patients receiving the devices – both now and in the future – so that these outcomes can be adequately assessed. In the United Kingdom, a minimum dataset has been agreed upon for patients having TAVI by the national cardiology and surgical societies; data collection is mandated before a centre is recognised for payment of the procedure.

The most important features of a TAVI device will change depending on the type of patient receiving the device. In an 85 year old with symptomatic severe aortic stenosis with multiple comorbidities the most important feature will be deliverability of the device. Paravalvular leakage after implantation and the robustness of the device may be less important. However, the issues for a 70 year old with no comorbidities will be very different, with the absence of paravalvular leakage post-procedure and long term results being the most important features. The cost effective balance will also be very different in these two patient groups. In the former scenario, the patient will either not receive surgery at all, and face multiple clinical re-admissions, or will undergo high risk surgery with long hospital stays in the intensive care unit. It is likely that the TAVI procedure (despite the cost of the device) will prove cost effective in this patient group. In the low risk surgical patient, hospital stay is generally short with possibly no time spent on the intensive care unit. In this group cost effectiveness will be difficult to prove. Therefore, for registry data to be effective in helping the development of the technique, it is important that both procedural outcome and costs of the index event are efficiently recorded. In addition, chosen centres for such a registry should submit all data on sequential patients. In order to fully asses risk this should include all patients referred to a unit for the treatment of aortic stenosis, whether the final decision is "medical therapy", surgical therapy or TAVI. This may be the only true means of acquiring an adequate dataset which will allow risk assessment across high risk patients.

We, as co-lead investigators for the Edwards SOURCE Registry urge our colleagues throughout Europe to participate in such endeavours with the requisite commitment of time and resources necessary to produce robust and believable prospective registry and clinical trial data which will guide clinical practice. Of course, the best data is that of a randomised trial. One is currently underway with SAPIEN valves in the US and others are planned. The unprecedented results of the control cohorts (patients turned down for surgery and surgery in "high risk" patients) will provide the first real benchmarks for TAVI. This is a breakthrough technology but the responsible roll-out into the real-world environment requires a commitment from the interventional and surgical community to commit the required resources to top quality data collection in both registries and randomised clinical trials.

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