

Monitoring Outcomes of Novel Interventions: The Case for Comprehensive Data Collection

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Major advances have been made within the last decade in the percutaneous treatment of valvular heart disease. Initially targeting high-risk or inoperable patients, transcatheter aortic valve implantation (TAVI) for senile calcific aortic stenosis has now been shown to be at least as good as surgical aortic valve replacement in intermediate-risk, and very recently in low-risk patients [1]. The treatment of mitral regurgitation, however, is much more complex and while numerous technologies for repair and replacement are in the development or testing stages, percutaneous mitral valve repair using the MitraClip System (Abbott Vascular, Menlo Park, CA, USA) device is by far the most commonly used and best validated [2]. To date, over 85,000 MitraClips have been implanted worldwide and over 600 of these in Israel. A growing number of clinical registries have reported on outcomes of MitraClip implantation in high-risk patients [3,4]. The results have shown consistent improvement in symptoms, reduction of New York Heart Association (NYHA) class, and decrease in recurrent hospitalizations.

Recently, two randomized controlled trials (RCTs) reported the outcomes of patients with heart failure and functional mitral regurgitation in patients who were randomized to medical therapy with or without MitraClip implantation. Although a smaller study was essentially negative [5], a larger study [6] showed a significant reduction in the primary composite endpoint of heart failure hospitalization and death at 2 years,

and a significant reduction in total mortality over 2 years of follow-up. The widely disparate results of these two trials most probably stem from differences in patient selection. In this edition of *Israeli Medical Association Journal (IMAJ)*, Schwartzberg and colleagues [7] reported on their single center experience with 39 MitraClip procedures in 37 patients. Procedural success was attained in 86% and 1-year survival was 86%. A modest improvement in functional class and a drop in pulmonary artery pressures were noted. Procedural complications and periprocedural mortality were uncommon. These findings correspond with contemporary reports and the two randomized controlled trials.

The importance of tracking procedural results locally is underscored by the disparate results of the RCTs. The onus is on us to understand which patients in real-world practice benefit from these technologies. Universal long-term follow-up of all patients undergoing procedures should be the standard of care and is essential for new technologies. Schwartzberg's group is to be commended for performing meticulous follow-up of their patients and for sharing these results with the medical community. However, single-center reports are not enough and this fact has been acknowledged by the Israeli interventional cardiology community. The Israeli MitraClip Registry was formed to fill this gap. This multi-center registry was established in January 2019 with the aim of collecting long-term prospective data on all patients undergoing MitraClip implantation in Israel. The operator-initiated registry depends on the voluntary collaboration of all implantation centers in Israel. Data accrued will enable medical professionals to evaluate patient selection for the procedure as well as assess procedural

and long-term echocardiographic and clinical outcomes. These data will enable centers to monitor their own results and compare them with other local centers. Importantly, we will be able to perform analyses on specific subgroups and better understand which groups obtain procedural success and which groups enjoy long-term clinical improvements. In the age of big data, ongoing monitoring of interventional procedures should become the norm, not the exception.

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