Rapid deployment aortic valves and minimally invasive aortic valve replacement: A perfect marriage of technology and technique?

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Since the first aortic valve replacement (AVR) through a right thoracotomy was reported in 1993, upper hemisternotomy and right anterior thoracotomy have become the predominant approaches for minimally invasive AVR (MIAVR).^{1,2} Clinical studies have documented comparable operative mortality, less bleeding, reduced pain, and shorter intensive care and hospital stays relative to conventional sternotomy.^{1,3-9} Accessing the aortic valve through a minimal access incision can be technically demanding, however, and longer procedural times are the rule.⁴ This may have significant clinical implications, because associations of major postoperative morbidity and mortality with prolonged procedural times have also been reported in the literature.^{10,11} Reducing the procedural times during MIAVR may therefore be of importance for improved postoperative clinical outcomes. Since the first implantation of sutureless aortic valves in the 1960s, recent technologic advances have made it possible to develop a new class of prosthetic heart valve substitutes, called *rapid deployment aortic valves*, which are intended to reduce procedure times and simplify conventional AVR operations. In the recent years, 3 different rapid deployment aortic valves have been introduced in Europe for use in both conventional AVR and MIAVR operations: the ENABLE Valve System (Medtronic, Inc, Minneapolis, Minn), the PERCEVAL S Valve System (Sorin Biomedica Cardio Srl, Sallugia, Italy), and the EDWARDS INTUITY Valve System (Edwards Lifesciences, Irvine, Calif). Favorable clinical outcomes with the use of these valves have been reported in several studies.¹²⁻¹⁴

In this issue of the *Journal*, Schlömlischer and colleagues provide a perspective from a center experienced in MIAVR on the use of the EDWARDS INTUITY Valve System, which received European CE mark in February 2012. In this study, 60 patients underwent MIAVR with the

EDWARDS INTUITY Valve System through an upper hemisternotomy approach. Mean age was 75.5 years, and mean log euroSCORE was 8.4. Technical success rate was 98.1%. Mean crossclamp and cardiopulmonary bypass times were 26 minutes (range, 16-47 minutes) and 56 minutes, respectively. Importantly, the mean duration from first valve stitch to tying the final knot after valve deployment was only 9 minutes. Early and late valve-related mortalities were 1.7% and 3.4%, respectively. No cases of late valve explantation, endocarditis, hemolysis, or structural valve deterioration were observed. At 1 year, valve hemodynamic performance was excellent, with an overall mean pressure gradient and a mean effective orifice area of 10.3 mm Hg and 1.8 cm², respectively. In particular, for the 21-mm valve (n = 17), mean gradient and effective orifice area were 10.2 mm Hg and 1.5 cm², respectively. Overall, the hemodynamic performance and safety outcomes observed at 1 year were favorable, with shorter procedural times and a high technical success rate, despite the added complexity of the minimally invasive approach. Rapid deployment aortic valve replacement through the use of the EDWARDS INTUITY Valve System has the potential to simplify MIAVR by reducing procedure times as the result of fewer sutures and faster implantation.¹⁵

Schlömlischer and colleagues report 1 case (1.7%) of moderate paravalvular leak (PVL) after weaning from cardiopulmonary bypass and no late PVL (>1+) beyond the first 30 days. In the surgical AVR control arm of the Placement of Aortic Transcatheter Valves (PARTNER) trial, moderate or severe PVL rates were 1.9% at 1 year and 0.9% at 2 years.¹⁶ In the Surgical Treatment of Aortic Stenosis With a Next Generation Surgical Aortic Valve (TRITON) trial,¹⁷ in which the EDWARDS INTUITY Valve System was implanted in 287 patients through either a MIAVR or a full sternotomy approach, the rate of moderate or severe PVL was only 1.2% at 1 year. These results are similar to that of the study of Schlömlischer and colleagues but are in contrast to the rates of major PVL observed with other rapid deployment AVR devices, which range between 6.7% and 19.4%.¹⁷⁻²⁴ Studies have correlated significant PVL with a higher risk of late mortality after transcatheter AVR, and the management of PVL by reoperation also carries a substantial risk.²⁵ The EDWARDS INTUITY Valve System, either implanted through a conventional full sternotomy or minimally invasive approach, appears to be associated with rates of moderate or severe PVL equivalent to those of surgically implanted heart valves. This may be associated with

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improved late mortality and fewer reoperations relative to other rapid deployment AVR devices.

New permanent pacemaker implantation rates after surgical AVR and transcatheter aortic valve intervention have been reported to be between 3.0% and 8.5% and between 25.5% and 27.8%, respectively.²⁶⁻²⁸ In the study of Schlömmicher and colleagues, only 1 case of new permanent pacemaker implantation (1.7%) was reported. This rate falls below the expected ranges for permanent pacemaker implantation after both surgical AVR and transcatheter aortic valve intervention and compares favorably with those seen with rapid deployment AVR devices other than the EDWARDS INTUITY Valve System, which have ranged between 7% and 17% in several studies.^{12,22,23,29}

In conclusion, this early experience with the EDWARDS INTUITY Valve System demonstrates that short cross-clamp and cardiopulmonary bypass times can be achieved with MIAVR. Further, excellent valve hemodynamic performance, with low rates of significant PVL and new permanent pacemaker implantation, can be expected. These data suggest that favorable clinical outcomes can be achieved despite the technically demanding nature of the minimally invasive approach. Certainly, I look forward to seeing these excellent clinical results replicated in other single-center and multicenter studies of MIAVR, with this device and also with other devices, and not only with a partial sternotomy approach but also through a right thoracotomy. If these results hold true, then the advent of rapid deployment aortic valves may indeed represent the perfect marriage between technology and technique.

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