

TAVI in centers without on-site cardiac surgery. Need or dare?

TAVI en centros sin cirugía cardiaca in situ. ¿Necesidad o temeridad?

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Since its incorporation into routine clinical practice more than 20 years ago, transcatheter aortic valve implantation (TAVI) has progressively gained acceptance within the cardiology community, driven by a successful and comprehensive clinical program that began with early reports in inoperable¹ and high-risk patients,² around 2010.

From the earliest studies, patient eligibility for TAVI was determined by a multidisciplinary committee of cardiologists and surgeons—which came to be known as the heart team—and procedures were performed exclusively at centers with on-site cardiac surgery. Similarly, all subsequent clinical practice guidelines on the management of TAVI have assigned the highest level of recommendation to performing the procedure in centers with a heart team and on-site cardiac surgery, a requirement that has persisted through the most recent European clinical practice guidelines.³

On the other hand, the marked increase in the number of procedures is making it difficult for hospitals with on-site cardiac surgery to meet this growing demand, thereby considerably prolonging waiting times—an especially sensitive issue given the high mortality rate of patients in this situation, which may exceed 15%.⁴ Therefore, it may be time to ask the following question: is the presence of a cardiac surgery department at the center still a prerequisite for establishing a TAVI program?

In an article published in *REC: Interventional Cardiology*, Rocha de Almeida et al.⁵ present their experience with 300 patients undergoing TAVI at a center without on-site cardiac surgery. Despite the absence of on-site cardiac surgery, what is striking at first glance is that this is a regional referral center with an interventional team experienced in performing the procedure at high-volume centers. Thus, this represents an initial experience for the center, but not for its operators.

In this series of 300 TAVI procedures performed over approximately 4 years, outcomes were comparable to those of high-volume centers; despite an advanced mean age (82 years), a mean Society of Thoracic Surgeons (STS) score of 3.8, and 17% of patients being categorized as high risk (STS score > 8), the 30-day mortality rate (primary endpoint) was 3.7% and the in-hospital mortality rate, 2%, with no conversions to surgery, annular rupture, coronary obstruction, or prosthetic embolization, and only 2 cases of percutaneous pericardiocentesis were required due to guidewire perforation.⁵

In fact, compared with the Portuguese registry,⁶ the 30-day mortality rate was numerically lower (3.7% vs 4.8%; $P =$ not significant [NS]), as was the stroke rate (2.7% vs 4.6%; $P =$ NS), with similar rates of bailout cardiac surgery (0 vs 0.4%), comparable vascular complications (8% vs 6.8%; $P =$ NS), and an identical rate of permanent pacemaker implantation (20% vs 19%).

Similar experiences have been reported in the literature from other countries, with varying sample sizes and generally retrospective designs (table 1). The earliest published experience of TAVI without on-site cardiac surgery was reported by Eggebrecht et al.^{7,9} using data from the German registry and comparing the outcomes at centers with a “visiting” surgeon with those obtained at centers with on-site cardiac surgery, without any differences being reported in the 30-day mortality rate (6.2% vs 8.3%; $P =$ NS) and with very low rates of bailout surgery (2.2% vs 1.6%). This experience has been replicated in other countries, such as Austria,⁸ with similar mortality rates in centers with and without on-site cardiac surgery (6.9% vs 6.2%; $P =$ NS), and Spain,¹⁰ with a comparable 30-day mortality rate (6.1%) and a very low rate of bailout surgery (0.3%). In more recent registries including lower-risk patients, such as the Israeli experience,¹¹ the 30-day mortality rate can be as low as < 1%.

As optimistic as these registries may appear when initiating a TAVI program without on-site cardiac surgery, the importance of care organization for this purpose must not be overlooked. High-volume centers with on-site cardiac surgery have the advantage of hospital-wide adaptation to this type of procedure, as well as training of all involved specialties, including cardiology, cardiac surgery, anesthesia, and intensive care. The authors highlight two critically important aspects: when they initiated the program, they already had extensive experience in TAVI, and the center served as a regional cardiology referral institution. Assuming that a TAVI program without on-site surgery can be initiated without all necessary safeguards would simply place patients at risk.

A notable feature of contemporary practice is that refinement of procedural steps, improvements in materials, enhanced team training, and supervision by experienced operators during program initiation have resulted in excellent TAVI and very low complication rates,¹² particularly in patients with low STS scores. Furthermore, performing this procedure at centers without on-site surgery has different implications in high-risk patients with limited surgical bailout options than in low-risk patients, in whom bailout surgery remains feasible, although infrequent and usually

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Table 1. Studies on TAVI in centers with and without on-site cardiac surgery

Study	Country	Patients		Vascular complications		30-day mortality rate		Bailout surgery	
		In centers without on-site cardiac surgery (n)	In centers with on-site cardiac surgery (n)	In centers without on-site cardiac surgery (%)	In centers with on-site cardiac surgery (%)	In centers without on-site cardiac surgery (%)	In centers with on-site cardiac surgery (%)	In centers without on-site cardiac surgery (%)	In centers with on-site cardiac surgery (%)
Eggebrecht et al. ⁷	Germany	178	1754	18.5	22.2	6.2	8.3	2.2	1.5
Egger et al. ⁸	Austria	290	290	9.3	4.8	6.9	6.2	—	—
Eggebrecht et al. ⁹	Germany	550	550	—	—	1.8*	2.9*	—	—
Roa Garrido et al. ¹⁰	Spain	384	—	—	—	6.1	—	0.3	—
Barashi et al. ¹¹	Israel	149	—	0.67	—	0.67	—	0	—

* In-hospital mortality.

associated with unfavorable outcomes.¹² Therefore, careful patient selection appears mandatory, with the participation of a heart team capable of determining eligibility for TAVI at centers without on-site surgery and auditing outcomes.

Further insight may be provided by the new prospective Italian registry TAVI at Home,¹³ which will include a total of 200 patients undergoing TAVI at centers without on-site surgery under strict inclusion and exclusion criteria (> 75 years, high or prohibitive risk, non-bicuspid valves, and no degenerated surgical valves) always under the scrutiny of a heart team including cardiac surgeons, clinical cardiologists, interventional cardiologists, imaging specialists, and anesthesiologists.

Moreover, in Italy, the randomized TRACS trial is underway, comparing TAVI performed at centers with vs without on-site cardiac surgery,¹⁴ with a planned enrollment of 566 patients and inclusion and exclusion criteria very similar to those of the TAVI at Home registry.

In conclusion, and in response to the question posed in this editorial, we firmly believe that performing TAVI at centers without on-site cardiac surgery is, without question, a necessary step. Accordingly, strict requirements and systematic outcome auditing are essential to ensure that this necessity does not translate into undue risk.

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CONFLICTS OF INTEREST

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