Rapid-deployment bioprosthetic aortic valve replacement; There is a flag on the field!

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In the current issue of the *Journal*, Sohn and colleagues¹ report the results of a meta-analysis of the literature on the clinical use of rapid-deployment or sutureless bioprostheses. In their analysis, which regrouped data from 21 different clinical studies, 1297 patients who underwent implantation of rapid-deployment or sutureless bioprostheses, essentially the Perceval S (Sorin Group, Milan, Italy) and the Edwards Intuity valve (Edwards Lifescience Corp, Irvine, Calif), were compared with 1488 patients who underwent aortic valve replacement with standard aortic bioprostheses. Only 2 of the studies were true randomized clinical trials. Of interest, the risk of significant bias between the 2 groups was graded as severe or moderate for 19 of the 21 studies included in the meta-analysis.¹

As expected, patients undergoing implantation of rapid-deployment or sutureless bioprostheses had significantly shorter cardiopulmonary bypass and crossclamp times. In our experience, we also reported shorter operating room and total surgical times.^{2,3} Rates of paravalvular leak appear similar for the 2 groups, but the need for permanent pacemaker insertion was higher in the group undergoing implantation of rapid-deployment or sutureless bioprostheses. Overall, perioperative mortality and morbidity were similar. Sohn and colleagues¹ concluded that we should be careful because of the higher need for permanent pacemaker implantation after surgery.

The study of Sohn and colleagues¹ is interesting, but is it really lifting the fog⁴ around these newer rapid-deployment bioprostheses? In fact, data for only 144 from the 2785 (5%) studied patients were extracted from randomized trials. The analysis of Sohn and colleagues¹ is based on heterogeneous groups of patients, different methods of determining prospective and retrospective cohorts, different baseline patient characteristics, and different statistical approaches. Sometimes, summarizing diverse and rather incomplete data leads to more confusion, rather than to clarification.

Michel Carrier, MD (left), and Denis Bouchard, MD, PhD (right)

Central Message

The red flag on rapid-deployment bioprosthesis will disappear only after completion of well-designed clinical trials comparing them with standard ones implanted through minimally invasive approaches.

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The use of rapid-deployment and sutureless prostheses not only decreases surgical time but also facilitates minimally invasive approaches, leading to reduced need for blood transfusion, shorter intubation time, and optimal hemodynamic profile.³ The higher rate of permanent pacemaker implantation remains an issue in need of proper assessment; is it due to a learning curve with the products, or is it inherent in their design? With the explosion of transcatheter aortic valve replacement, there is a red flag on the field of surgical aortic valve surgery. Clinicians need to innovate; minimally invasive approaches and prostheses facilitating the use of these techniques should be experimented with and tested with appropriate study designs. We should also plan head-to-head comparisons of minimally invasive surgery combined with rapid-deployment prostheses versus transcatheter aortic valve replacement.

The red flag and the fog will disappear only after the completion of well-designed clinical trials that compare rapid-deployment and standard bioprostheses implanted through minimally invasive approaches. The new standard of care in surgical aortic valve replacement may well turn out to be these newer facilitating prostheses! The tipping point toward a change in clinical practice should be based on proper trials in addition to long-term durability data.⁵

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