

EDITORIAL COMMENT

The Minimalist Approach for Transcatheter Aortic Valve Replacement in High-Risk Patients*

Danny Dvir, MD,† Rajiv Jhaveri, MD,‡
Augusto D. Pichard, MD†

Washington, DC

The Rouen Group needs to be congratulated for an impressive series of transcatheter aortic valve replacement (TAVR) cases performed with the “minimalist approach”: no general anesthesia (GA), no transesophageal echocardiography (TEE) guidance. Almost exactly 1 decade ago, in April 2002, Professor Alain Cribier led the first human TAVR performed in a compassionate case and did it with the patient under conscious sedation (CS) and local anesthesia (1). Aortic valve implantation with a percutaneous approach obviates the need for sternotomy, cardiopulmonary bypass, and manipulation of the ascending aorta. This approach might also eliminate the need for tracheal intubation and GA.

See page 461

In this issue of *JACC: Cardiovascular Interventions*, Durand et al. (2)—from the same pioneering group in Rouen, France—share their experience of performing transfemoral TAVR in 151 consecutive cases with the Edwards SAPIEN and SAPIEN XT transcatheter heart valves (Edwards Lifesciences, Irvine, California) with exclusively CS with modest doses of intravenous (IV) midazolam and nalbuphine and fluoroscopic guidance, without TEE. The combined 30-day safety endpoint was reached in 15.9%, including a death rate of 6.6%, comparable to other large TAVR series. Conversion to emergent cardiovascular surgery was performed in 5 cases (3%) and only when using the old SAPIEN version (Edwards Lifesciences). Conversion to

GA in the catheterization laboratory was used in only 1 case. In no patient was GA needed due to complications of IV sedation or lack of patient cooperation.

In the United States most TAVRs are performed with GA. In a recent survey exploring anesthetic practices during transfemoral TAVR, only 5% of the 61 North American centers employ CS routinely, whereas in Europe 68.4% of centers are now performing TAVR under CS (Bufton K et al., personal communication, January 2012).

The minimalist approach of local anesthesia and CS is obviously attractive in frail, elderly, high-risk patients. It is assumed that when using minimal amounts of sedative agents, the hemodynamic effects attributable to these drugs will be minimal as well. Although inotropic requirements to correct hemodynamic changes secondary to procedural interventions, such as rapid atrial pacing and balloon valvuloplasty, cannot be avoided, the overall need for inotropes should be lower. Conscious sedation allows the monitoring of neurological status during the procedure, considered important because of the high stroke rate. Conscious sedation also offers evaluation of pain during dilator and sheath placement in the femoral artery. This evaluation plays an important role in knowing when to stop, because pushing the dilator or sheath in this scenario might lead to vascular complication. When CS with minimal sedation is used, patients are awake at the end of the procedure; thus, time spent in the intensive care unit and in-hospital is minimized. Moreover, because many of these high-risk patients have chronic pulmonary disease, complications of prolonged ventilation are avoided.

Anesthetic management during TAVR procedures has been the subject of controversy. Most of the important trials and large registries, unfortunately, do not give data on anesthetic management during the procedures. There are only a few trials designed to evaluate the appropriate anesthetic management during transfemoral TAVR (3–7). Most publications fail to provide details with regard to the amounts and types of drugs used for IV sedation or the depth of sedation achieved or targeted. Thus, it is difficult to make an informed evidence-based choice about the best anesthetic management practice in this group of patients. One large registry of 663 TAVR cases included data contrasting CS with GA, which showed that the mortality rate in the CS group was lower than in the GA group (15% vs. 23%, $p = 0.02$) (8). Nevertheless, the anesthetic approach was not an independent predictor for mortality after multivariate analysis. In a recent trial by Bergmann et al. and in several other nonrandomized trials (3–7), CS showed similar clinical results compared with GA. A similar experience was reported in endovascular aortic aneurysm repair, with shorter procedural time and hospital stay in those with CS as compared with GA (9).

In our center most of the transfemoral TAVR procedures are performed with the “Rouen Approach” employing CS.

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From †Interventional Cardiology, Washington Hospital Center, Washington, DC; and the ‡Department of Anesthesia, Washington Hospital Center, Washington, DC. Dr. Pichard has served as proctor for Edwards Lifesciences. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

All of our patients had TEE guidance, however, as mandated by the PARTNER protocol. Transesophageal echocardiography has been performed under CS in our catheterization laboratory for more than 20 years. Many centers prefer GA due to the presence of a TEE probe with its high level of nociceptive stimulation. Our cardiac team, including anesthesiologists, does not see TEE as a mandatory indication for intubation. We previously reported a series of consecutive high-risk patients undergoing transfemoral TAVR under GA or CS (10). Procedures performed under CS produced a lower in-hospital death rate, shorter procedure duration, and shorter hospital stay than those performed under GA (Fig. 1 in Durand et al. [2]). Among the first 230 patients at our center, 158 had the device inserted through the iliofemoral vessels. Twenty patients (12.7%) converted to GA. Baseline clinical characteristics of the 2 groups were similar, except for higher logistic EuroSCORE (European System for Cardiac Operative Risk Evaluation) in the CS group (39.6 ± 19.7 vs. 31.1 ± 18.5 , $p = 0.02$).

Is CS a better approach for most patients undergoing transfemoral TAVR? The results depicting the safety of CS come from an experienced team and might not be reproducible for other groups, especially at the beginning of their learning curve. Moreover, because all the data we have—including that from Durand et al. (2)—come from nonrandomized trials, we should view it as “hypothesis generating” only. It is time to critically evaluate the anesthetic techniques to guide the anesthesiologists who care for these patients.

Although the Rouen Group had an anesthesiologist available, he/she was not present in the catheterization laboratory. In our group the cardiac anesthesiologist is in charge of CS and is an active member of the team managing the patient during TAVR. We support the message coming from Rouen and encourage TAVR centers to collect anesthesia-related data to help us make an educated choice when selecting the optimal anesthetic approach for each of the patient subgroups undergoing these procedures.

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Reprint requests and correspondence: Dr. Augusto D. Pichard, Washington Hospital Center, 110 Irving Street, North West, Washington, DC 20010. E-mail: guspichard@gmail.com.

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