# Study finds moderate sedation more effective than general anesthesia for TAVR patients

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A new study finds the use of moderate sedation, in which patients do not need a breathing tube, leads to better clinical outcomes as compared to general anesthesia for patients undergoing transcatheter aortic valve replacement (TAVR). Researchers from the Perelman school of Medicine at the University of Pennsylvania conducted the largest observational study of minimally invasive transfemoral—entry through the groin—TAVR to find whether the use of moderate sedation is associated with improved patient outcomes, specifically evaluating 30-day mortality and length of hospital stays, as compared to traditional general anesthesia. Their findings were presented today as a late-breaking clinical trial at the Society for Cardiovascular Angiography and Interventions 2016 Scientific Sessions in Orlando, FL.

For patients who are at extreme or high risk for open heart surgery, TAVR, a minimally invasive procedure, has become the preferred therapy for severe aortic stenosis. While general anesthesia has been typically administered during these cases, the use of moderate sedation for TAVR is increasing. Most of the developments associated with TAVR over the past decade have been focused on the device, technology and procedural techniques. However, there has been a push to improve the process of the procedure.

"More recently the field has moved toward use of an even more minimally invasive TAVR procedure, in which physicians are able to insert the new valve through the groin with no incisions at all," said senior and presenting author Jay Giri, MD, MPH, an assistant professor

of Cardiovascular Medicine. "Since there is no longer a definitive need for a surgical incision, we had to ask the question of whether there was a need for general anesthesia, the full sedation of a patient requiring breathing tube and nonresponsive unconsciousness."

Researchers used the STS/ACC TVT RegistryTM - a database of all United States TAVR patients - to evaluate elective cases treated via a percutaneous transfemoral approach—entry through the groin without an incision— from April 2014 through June 2015, in order to compare the effectiveness of moderate sedation to general anesthesia. A total of 10,997 patients were assessed with 1,737 receiving moderate sedation - approximately 15.8 percent. Investigators concluded that while both patient groups had nearly equal rates of TAVR procedural success, moderate sedation patients experienced lower rates of 30-day mortality, 30-day mortality or stroke, and briefer hospital stays.

"This data shows that moderate sedation is both safe and effective, and has potential to become the choice approach for TAVR," Giri said. "These results support our hypothesis that moderate sedation can lead to better clinical outcomes, and could have significant implications for patient care and for the process of the TAVR procedure."

Importantly, the researchers also conducted a propensity-matched analysis which accounted for 51 factors known to predict 30-day TAVR mortality, such as age, gender and heart failure status. The analysis further confirmed that moderate sedation was associated with lower 30-day mortality and 30-day mortality or stroke.

"This additional analysis was conducted in order to evaluate whether moderate sedation is successful across a variety of patients, and not just a relatively healthy group that was selected for this novel technique," Giri said. "While it is nearly impossible to account for all factors that could lead to needing general anesthesia, the 51 comorbidities and

clinical characteristics we were able to account for still brought us to the same outcome - moderate sedation is associated with better clinical outcomes for patients undergoing percutaneous transfemoral TAVR."

Giri noted that there are three levels of moderate sedation: isolated local anesthesia at the entry site; conscious sedation, or "twilight sleep" which puts patients into a very light, responsive sleep; and monitored anesthesia care - used by the Penn TAVR team - in which anesthesia is administered in different proportions by a certified anesthesiologist, putting patients into an unconscious, but arousable state.

Provided by University of Pennsylvania School of Medicine

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