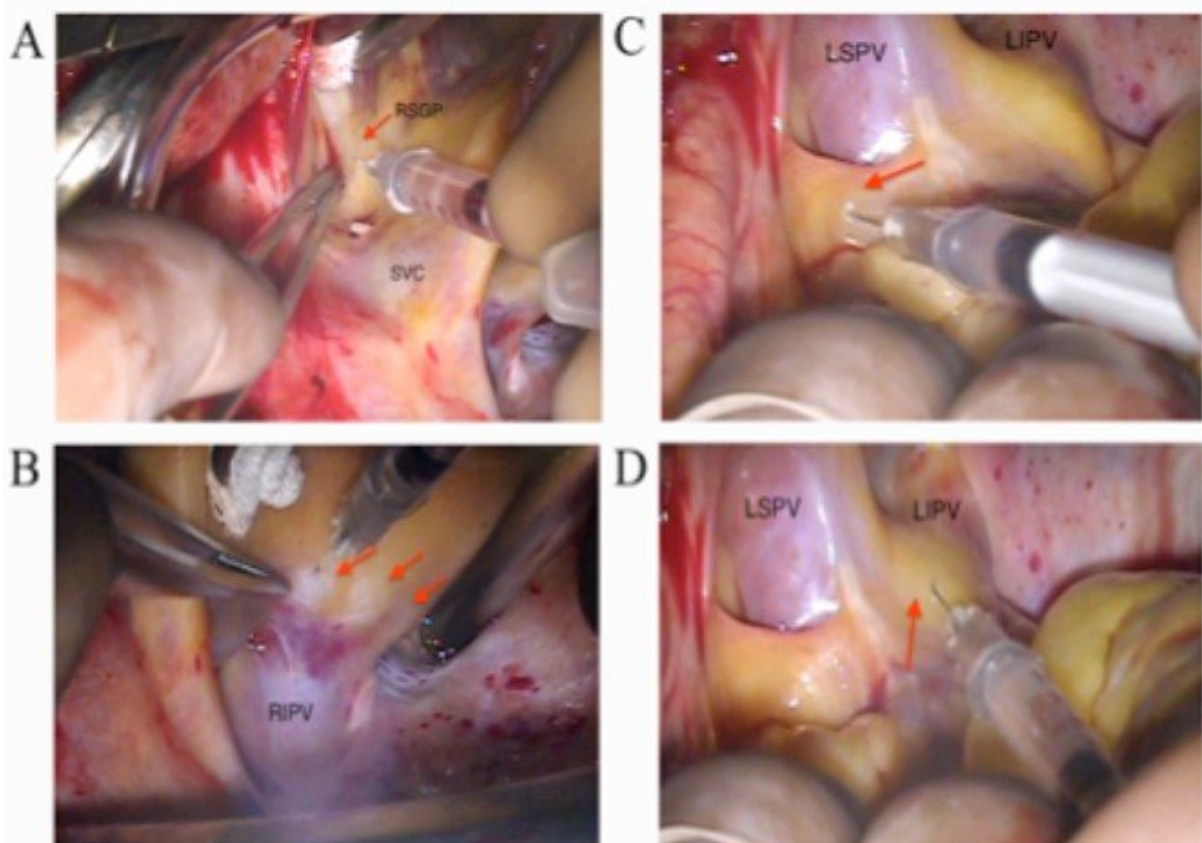


Botulinum toxin shows promise in trials to reduce post-operative atrial fibrillation (POAF) in cardiac surgery patients

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View from surgeon's perspective of the injection of botulinum toxin into each of the epicardial fat pads near each pulmonary vein. Credit: *Heart Rhythm*

Postoperative atrial fibrillation (POAF) is a common complication, affecting one quarter to one half of all patients following cardiac surgery. It can result in heart failure, stroke, and longer hospital stays, resulting in an increased cost of care. *HeartRhythm*, the official journal of the Heart Rhythm Society and the Cardiac Electrophysiology Society, reports promising results from two clinical trials using botulinum toxin (BTX) injections to suppress POAF.

BTX, a potent inhibitor of neural transmission, is best known for its use in temporarily reducing facial wrinkles. The global cosmetic market for BTX was estimated at US \$3.4 billion in 2015. It is also used to treat some neurological disorders including excessive sweating and eye muscle disorders.

In a randomized placebo-controlled [longitudinal study](#) of 60 patients undergoing coronary artery bypass graft surgery, patients who received BTX injections during surgery showed a sustained reduction in the incidence and overall burden of atrial fibrillation (AF) over three years of follow-up, accompanied by a reduced need for hospitalization. BTX was injected into each of the epicardial fat pads near each pulmonary vein.

Senior investigator Jonathan S. Steinberg, MD, of the Heart Research Follow-up Program, University of Rochester School of Medicine & Dentistry, Rochester, NY, USA, explains, "This study tested the hypothesis that interruption of cardiac neural traffic by BTX could undermine the pathologic processes that promote AF after [cardiac surgery](#). In two previous publications, the study group has shown significant reductions in early postoperative AF up to 30 days, but also sustained reduction of AF out to one year."

In the current study, AF events were captured by implantable cardiac monitors in all patients. The incidence of AF was reduced by 64 percent

in patients who received BTX. Further, the overall burden of AF was reduced five- to nine-fold in each year of follow-up. Over three years, the number of patients who required hospitalization for AF, the total number of hospitalizations, and the need for drug therapies or additional procedures were all reduced in the BTX group.

"The results of our studies suggest a new approach to treatment of AF," says Dr. Steinberg. "The sustained reduction of AF, now demonstrated over three years, was notable and a bit of a surprise. We believe that autonomic remodeling was interrupted and the predisposition to AF was reset as a result of BTX injection." The BTX concept could also be tested in non-postoperative patients in future studies, extending the treatment paradigm of neuromodulation as a stand-alone or supplemental antiarrhythmic strategy, which may potentially be applicable to the many other clinical contexts in which AF appears.

According to Dr. Steinberg, this is potentially an important and impactful breakthrough if confirmed in larger trials. If postoperative AF is reduced, there may be significant reduction in the utilization of health care resources, an important goal for healthcare systems under stress because of high costs. There may also be long-term clinical and financial benefits.

In the second trial reported in this issue, Nathan H. Waldron, MD, MHS, of the Department of Anesthesiology, and colleagues at Duke University, Durham, NC, USA, randomized 130 patients to receive an injection of either 250 units of botulinum toxin type A (BoNTA) or saline in epicardial fat pads containing autonomic ganglia after the start of cardiopulmonary bypass, but before the surgical procedure. They assessed the occurrence of POAF with continuous telemetry during postoperative hospitalization. There was no increase in complications after cardiac surgery, but the procedure did not result in a statistically significant reduction in the risk of POAF. The investigators consider this

may be due to inadequate power to detect a modest, but clinically meaningful, impact of BoNTA.

"While we did not observe a statistically significant reduction in the occurrence of POAF, patients receiving epicardial botulinum toxin had shorter initial episodes of POAF and a trend toward less hemodynamically significant POAF," notes Dr. Waldron.

"The patients treated with toxin had an 11 percent lower risk of post-operative AF that did not meet statistical significance, so a larger, adequately powered trial is something that is needed to provide a clearer picture," adds senior author Jonathan P. Piccini, MD, a member of the Duke Clinical Research Institute (DCRI), Durham, North Carolina, USA.

In an accompanying editorial, Joris R. de Groot, MD, Ph.D., of the Department of Cardiology, Heart Center, Amsterdam University Medical Centers, University of Amsterdam, The Netherlands, examines the different outcomes of the two studies and points out some key differences. For example, the first study included only coronary artery bypass grafting (CABG) patients, whereas the second study also included patients undergoing valve or combined surgery. The atrial sizes were also different between these studies.

"Studies with [botulinum toxin](#) type A injection into the ganglion plexi remain confined to patients undergoing open-chest surgery, and a larger scale clinical trial with botulinum injection into the ganglion plexi in CABG patients is on the way," Dr. de Groot comments. "For AF treatment or suppression in [patients](#) not undergoing thoracotomy, nonthermal ablation appears a promising approach that proved tissue-specific, and merits further clinical investigation."

More information: Alexander Romanov et al, Long-term suppression

of atrial fibrillation by botulinum toxin injection into epicardial fat pads in patients undergoing cardiac surgery: Three-year follow-up of a randomized study, *Heart Rhythm* (2018). [DOI: 10.1016/j.hrthm.2018.08.019](https://doi.org/10.1016/j.hrthm.2018.08.019)

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