European experience of the convergent atrial fibrillation procedure: Multicenter outcomes in consecutive patients

Borut Geršak, MD, PhD,[a] Michael O. Zembala, MD, PhD,[b] Dirk Müller, MD, PhD,[c] Thierry Folliguet, MD, PhD,[d] Matevz Jan, MD, PhD,[a] Oskar Kowalski, MD, PhD,[b] Stefan Erler, MD,[c] Clement Bars, MD,[d] Boris Robic, MD,[a] Krzysztof Filipiak, MD,[b] and Gerhard Wimmer-Greinecker, MD, PhD[c]

Background: The objective of this collaborative, multicenter, European effort was to evaluate the outcomes of the convergent procedure for the treatment of persistent and long-standing persistent atrial fibrillation (AF) in consecutive patients at 4 European centers.

Methods: Outcomes of consecutive patients, undergoing the convergent procedure at 4 European centers, were evaluated in this study. Epicardial ablation was performed before endocardial ablation. Convergent procedure outcomes were recorded by interrogation of implanted loop recorders or Holter monitors. Rhythm status and required interventions (antiarrhythmic drugs, cardioversions, and repeat ablations) were quantified 6 and 12 months after the procedure. Outcomes, monitoring type, and patient baseline characteristics were analyzed and reported.

Results: Seventy-three consecutive patients presenting with persistent AF (30.1%) or long-standing persistent AF (69.9%) underwent the convergent procedure between January 2010 and December 2011. At 6 months, 82% (56/68) were in sinus rhythm. At 12 months, 80% (53/66) were in sinus rhythm; single-procedure maintenance of sinus rhythm without postblanking period interventions was 76% (50/66); 52% (34/66) were in sinus rhythm and not receiving antiarrhythmic drugs.

Conclusions: This multicenter European collaborative effort demonstrated that the convergent procedure is a safe and efficacious treatment option for persistent and long-standing persistent AF. (J Thorac Cardiovasc Surg 2014;147:1411-6)

Atrial fibrillation (AF) treatment needs new modalities to treat the most prevalent and complex forms of AF, persistent and long-standing persistent. Catheter ablation has become a primary treatment modality for drug refractory, symptomatic paroxysmal AF, but has demonstrated limited efficacy in persistent and long-standing persistent AF. The 5-year arrhythmia-free survival for a single catheter ablation procedure in a predominantly paroxysmal patient population has been reported at 29%, whereas the efficacy after multiple procedures was 63%.[1] Consequently, the incidence and recurrence of AF greatly exceed the number of patients successfully treated, causing explosive growth and a burden to health care systems around the world.[2]

Isolation of focal triggers associated with the pulmonary veins (PVs) is a cornerstone of any AF treatment strategy.[3,4] However, simple PV isolation does not address reentrant circuits associated with persistent and long-standing persistent AF or patients with structural heart disease and enlarged atria.[5] The posterior left atrium has become a target of interest in patients having chronic atrial stretch and AF because of observations of conduction abnormalities, including slower conduction, heterogeneity, and numerous lines of functional block.[6] Therefore, to treat the most prevalent complex forms of AF, an effective procedure must isolate the PVs and the posterior left atrium without hindering heart function or the ability of the heart to reverse remodel once sinus rhythm is restored.

The convergent procedure was developed to directly access and visualize the posterior left atrium to isolate the PVs and ablate the posterior left atrium while offering minimal surgical trauma combined with precision of the electrophysiologic 3-dimensional mapping. The multidisciplinary approach leverages the ability of the endoscopic surgeon to complete lines of conduction block with the electrophysiologist's ability to map the lines of block, identify breakthroughs, and complete isolation of the PVs. By combining these 2 disciplines, a comprehensive pattern of endocardial and epicardial lesions is created without chest incisions, lung deflation, or invasive heart

From the Department of Cardiovascular Surgery,[a] University Medical Center Ljubljana, Ljubljana, Slovenia; the Silesian Center For Heart Diseases,[b] Zabrze, Poland; the Herz-und Gefäßzentrum,[c] Bad Bevensen, Germany; and L'Institut Mutualiste Montsouris,[d] Paris, France.

Disclosures: Drs Gersak, Zembala, and Folliguet are consultants for nContact, Inc. The other authors have nothing to disclose with regard to commercial support.

Received for publication Feb 7, 2013; revisions received June 10, 2013; accepted for publication June 27, 2013; available ahead of print Aug 28, 2013.

Address for reprints: Borut Geršak, MD, PhD, Department of Cardiovascular Surgery, University Medical Center Ljubljana, Zaloska 7, 1000 Ljubljana, Slovenia (E-mail: bgersak@maat.si).

0022-5223/$36.00

http://dx.doi.org/10.1016/j.jtcvs.2013.06.057

ET/BS

Abbreviations and Acronyms
AF = atrial fibrillation
PV = pulmonary vein

dissections. The purpose of this article is to evaluate outcomes of the multidisciplinary closed chest convergent procedure for the treatment of persistent and long-standing persistent AF.

METHODS

This is an outcomes data evaluation study performed at 4 European centers in compliance with the Declaration of Helsinki. Local medical ethics committee approval was obtained by each site before study initiation. All patients with a history of persistent or long-standing persistent AF consenting to study participation were eligible for inclusion in the study. Seventy-three patients consented; consecutive AF patients underwent the convergent procedure at the 4 centers between January 2010 and December 2011. A 3-month blanking period was allowed; any AF treatments within this period were not considered efficacy failures, except any endocardial catheter ablations were recorded as redos.

Multidisciplinary AF Treatment

The epicardial and endocardial ablation components of the convergent procedure were performed as a single-setting procedure on the same day or as a staged procedure, with the epicardial and endocardial components performed on 2 different days, as 2 different hospitalizations. At one center, all the procedures were performed as staged procedures minimally 2 weeks apart to accommodate local reimbursement challenges. At a second center, 50% of the procedures were performed as staged procedures minimally 2 months apart.

Transdiaphragmatic Access and Epicardial Ablation

Endoscopic access to posterior cardiac structures was established through 3 small abdominal stab incisions. Low-pressure insufflation of the belly provided visualization of the central tendon portion of the diaphragm. Epicardial access was first obtained by creating a pericardial window with a shielded Teflon monopolar electrocautery hook probe (ATC Technologies, Wilmington, Mass) through the visualized central tendon of the diaphragm.[7] A transdiaphragmatic window to the pericardium allowed introduction of a soft shallow angle cannula (nContact, Inc, Morrisville, NC) into a retrocardiac position, giving a direct view of the posterior left atrium and allowing manipulation of the cannula without compromising hemodynamics. After accessing the left atrium, linear epicardial lesions were created along the posterior region of the left atrium.[8] At all 4 sites, preset power (30 W) and time (90 seconds) settings for the Numeris Guided Coagulation System (nContact, Inc) were used for the creation of each epicardial lesion.

Figure 1, *A*, shows the base lesion pattern. Posterior left atrial lesions were created between the left and right pulmonary veins within the oblique sinus that is outlined by the pericardial reflections. After ablating the posterior left atrium between the left and right pulmonary veins, linear lesions were created anterior to the left pulmonary veins toward the ligament of Marshall. Finally, lesions were created anterior to the right pulmonary veins and inferior vena cava parallel to the interatrial groove. After the creation of all epicardial lesions, the abdominal access sites were closed and the patient was prepared for standard left-sided endocardial ablation for the convergent procedures performed in a single setting.

Epicardial Ablation System

The Numeris Guided Coagulation System, designed for such closed-chest, thoracoscopic procedures, was used for the endoscopic visualization of the pericardial space and the creation of epicardial linear lesions. The epicardial ablation device and cannula used to access the pericardial space are shown in Figure 1, *B* and *C*.

Suction applied to the helical coil electrode ensures consistent and predictable contact with cardiac tissue during radio frequency ablation. A perfusion lumen coupled to the vacuum lumen is routed to an unpressurized bag of saline. Once a vacuum seal is obtained, saline is pulled along the device, cooling the surface of the instrument not in contact with the epicardium and focusing RF energy into the epicardium. This ensures a complete lesion that extends to the endocardium. The vacuum-controlled saline perfusion also provides a visible indicator that a vacuum seal has been maintained.

The design of the device solves the critical requirements for the creation of complete, nonconductive lesions capable of interrupting erratic electrical signals, as demonstrated by chronic good clinical practice preclinical studies.[9] The lesions are visible along the epicardial surface of the heart, allowing them to be easily connected under direct visualization into a pattern capable of interrupting and silencing deviant circuits. The radiofrequency generator uses an algorithm based on impedance that regulates power to prevent tissue overheating and subsequent vaporization.

The Numeris system has received the Conformité Européenne mark of approval for the coagulation of cardiac tissue using radiofrequency energy for the treatment of arrhythmias, including atrial fibrillation or atrial flutter.

Transseptal Access and Endocardial Catheter Ablation

Percutaneous venous catheterization was used to introduce catheters into the right atrium. A coronary sinus catheter was inserted to provide a reference for 3D navigation. A transseptal puncture was used to access the left atrium and introduce mapping and ablation catheters. Electrophysiologist mapping techniques, including interrogation of intracardiac electrograms with a Lasso catheter or voltage mapping with Carto3 (Biosense Webster, Diamond Bar, Calif) or NavX (St Jude Medical, St Paul, Minn), were performed to identify breakthroughs between epicardial lesions along the pericardial reflections. Endocardial lesions were created to connect the epicardial lesions and complete the pulmonary vein isolation. Each site used the endocardial catheter and mapping systems of its choice. In Slovenia, Celsius catheters were used without a navigation system, and with power set at 25 to 30 W and an irrigation rate of 60 mL/min when ablating and 2 mL/min when on standby. In Germany, Thermocool catheters (Biosense Webster) were used with either Carto or NavX mapping systems; endocardial ablation was performed at 20 to 30 W with an irrigation rate of 17 mL/min. In France, the Biosense Navistar irrigated catheter was used with the Carto mapping system; during endocardial RF ablation, power settings of 26 to 35 W were used, with 42°C as a target temperature and an irrigation rate of 17 and 22 mL/min. In Poland, the NaviStar catheter system (Biosense Webster) was used with the Carto 3-dimensional mapping system; endocardial ablation was performed with a power setting of 40 W for 60 seconds.

All sites performed entrance and/or exit block testing to ensure electrical isolation of the PVs and the posterior atria.

Postoperative Management

Antiarrhythmic drug therapy was directed by the referring physician throughout follow-up. Anticoagulation was reinitiated postoperatively and continued for at least 3 months, and was also directed by the referring physician. Postoperative pain management was at each physician's discretion. Level of pain was a subjective patient response from low to moderate levels. Hospital stay averaged 5 days for patients undergoing the convergent procedure in a single setting and the epicardial ablation procedure in the staged procedure setting. Hospital stay averaged 2 days for patients undergoing the endocardial ablation procedure in the staged procedure setting.

Follow-up Monitoring

A total of 65% (48/73) of patients were implanted with implantable loop recorders (Reveal XT Insertable Cardiac Monitors;