NOVEDADES

PERSPECTIVES

The Imminent Operationalization of the National Institute of Cardiology in Argentina

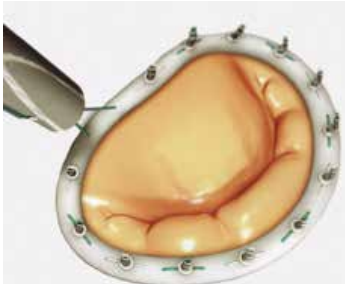
In the last Congress of the Argentine Society of Cardiology, the Vice-Minister of Health Néstor Pérez Baliño announced the delayed creation of the National Institute of Cardiology with the purpose of knowing and doing research into cardiovascular diseases in Argentina.[1] The implementing regulation of the law for the creation of this Institute will be possibly signed before the end of 2016 and become enforceable in 2017. The role of this Institute will be primarily to know about the health situation and to develop related prevention policies, to evaluate quality standards and to contribute to the design of the country's Universal Health Coverage Plan. Related scientific societies, such as the Argentine Society of Cardiology, the Argentine Federation of Cardiology and the Argentine College of Interventional Cardioangiologists, which could collaborate in the development of research programs, could be involved in the operation of the National Institute of Cardiology, and it is expected that the Argentine College of Cardiovascular Surgeons (CACCV) also participates. The CACCV should keep its eyes open for this new stage of cardiovascular health in Argentina and should promptly propose health ideas and public policies of interest to the new Institute. There are four basic areas on which to work within the field of cardiovascular surgery:

1) The collection of information about the number and type of surgical procedures performed per zone of the country, and the projected needs to fill coverage gaps and to meet the future demand;
2) The proposal and evaluation of quality standards of surgical procedures nationwide;
3) The participation in the evaluation and implementation of technological innovations in the specialization, as well as in the promotion of the local development of such technologies; and

4) The outline of guidelines and requirements to train human resources in cardiovascular surgery.

We need to be ready to support this initiative and to offer our ideas for the sake of the country's cardiovascular health.

1.http://www.telam.com.ar/notas/201610/166892-instituto-nacional-de-cardiologia-enfermedades-cardiovasculares-investigacion.html.



The Sale of the Automated Suture Fastening System Cor-Knot® in Argentina

The Cor-Knot Mini® technology (LSI Solutions, USA), which allows to automatically tie (actually fasten) suture stitches in a prosthetic valve replacement or a mitral valve annuloplasty, began to be sold in Argentina in October 2016. The device consists of a system of titanium clips or fasteners that slide over sutures, adjust threads and automatically trim away excess suture tails. While this system facilitates tying in the case of a minimally invasive approach where reduced space makes the manual task difficult, it is equally useful through a traditional sternotomy. For the time being, there are few reports in the literature; however, it has been suggested that these devices could shorten the time of robotically-assisted mitral surgery considerably.[1] Also, the strength, resistance and speed of this method in adjusting stitches were compared in laboratory animals to those of hand-tying, and very satisfactory results were achieved with Cor-Knot.[2-3] According to other authors, these titanium clips could also serve as a radiopaque marker of the valvular ring for an eventual future valve-in-valve implant,[4] or for some other kind of less frequent surgical indication.[5] Recently, we have had the opportunity to test this device in a mitral valve replacement. After the stitches in the valve and prosthesis rings, loading each pair of sutures in the system through a loop was very easy and quick, as well as unloading each fastener, providing a sense of safety and firmness in securing the prosthesis. In any case, more reports with remote follow-up will be needed to assess the usefulness and safety of the procedure.

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2. Lee CY, Sauer JS, Gorea HR, Martellaro AJ, Knight PA. Comparison of strength, consistency, and speed of COR-KNOT versus manually hand-tied knots in an ex vivo minimally invasive model. Innovations (Phila) 2014;9:111-6; discussion 116. doi: 10.1097/IMI.0000000000000051.

3. Lee CY, Wong JK, Ross RE, Liu DC, Khabbaz KR, Martellaro AJ, et al. Prosthetic Aortic Valve Fixation Study: 48 Replacement Valves Analyzed Using Digital Pressure Mapping. Innovations (Phila) 2016 Aug 25. [Epub ahead of print]

4. Czerny M, Sündermann S, Falk V. The Cor-Knot device may serve as an ideal radiopaque marker of the annular plane for future valve-in-valve implantation. Ann Thorac Surg 2014;98:1485-6. doi: 10.1016/j.athoracsur.2014.04.046.

5. Di Giammarco G, Foschi M, Di Mauro M. Cor-Knot automated fastener to facilitate Corex aortic valve bypass implantation. Asian Cardiovasc Thorac Ann 2015;23:1010-2. doi: 10.1177/0218492315594521.

The Failure of the First Leadless Pacemaker and the Premature Adoption of Innovations

Nanostim® Leadless Pacemaker (St. Jude Medical, Inc.) is a miniaturized single-chamber pacemaker (42 mm x 6 mm) with no leads that can be implanted into the right ventricle with an implant tool through a vein. The first clinical trial with 3-month follow-up (LEADLESS trial),[1-2] which assessed the safety of this new device, included only 33 patients with an implant success of 97% and a complication rate over 6%, although 15% of patients required more than one device or replantation for proper stimulation. Nanostim® was approved by the European Community in 2013, and the enrollment of patients in the clinical trial after approval began in March 2014 in Great Britain, Germany, Italy, Czech Republic, France, Spain and Holland. This LEADLESS II trial enrolled 667 patients, with an implant success of 95.8% and a complication rate of 6.7% (1.7% related to dislodgements, 1.3% to cardiac perforation, 1.3% to the need for a new implant, and 0.7% to vascular lesions). After a 6-month follow-up, the expected battery life was reported to be 15 years.[3] However, on October 28, 2016, St. Jude suddenly reported the suspension of the sale of Nanostim® due to problems with the battery of the device, the loss of telemetry and the switching-off of the pacemaker (7 cases in 1423 implants).[4] Given the number of implants to date, there would still be 1397 patients at potential risk of malfunction of this pacemaker. These unexpected events should make us reflect on the danger of the premature adoption of innovations in an area as sensitive as cardiovascular diseases and invasive treatments.

For the time being, the Micra® Medtronic Transcatheter Pacing System (TPS) is the other miniaturized leadless pacemaker that can be implanted in the same way. After an initial experience in animals,[5] a first clinical trial was conducted. By May 2015, 744 patients from 56 centers in 19 countries of North America, Europe, Asia, Oceania and Africa had already been enrolled. The authors concluded that the Micra® TPS could be implanted successfully in 99.2% of cases. The device reached the appropriate threshold criteria in 98.3% of the patients after a 6-month follow-up. While there were only 28 major complications (1.6% corresponded to ventricular perforations and 0.7% to vascular lesions), pre-established safety criteria were also met and 96.0% of patients did not present any complication after 6 months.[6] Based on this publication, on April 19, 2016, the FDA approved the first pacemaker that does not require leads to transmit the electrical pulse to the heart. During the 2016 Congress of the European Society of Cardiology, the company confirmed with new data that the risk of major complications after the implantation of the Micra® TPS remained at 4% on 12-month follow-up.

Although these devices have the advantage of avoiding complications related to the generator pocket and leads (including tricuspid failure) and the possibility of being implanted in the interventricular septum in order to reduce biventricular dyssynchrony, for now they only have VVI format, would not be easily removable in case of malfunction or endocarditis (only one out of three attempts to remove a Micra® with

a special catheter was successful),[7] may migrate and embolize to the lung, may puncture the ventricle, become encapsulated and eventually generate thrombus in the right cavities.[8-9] For the time being, more mid- and long-term results should be expected before adopting this new technology prematurely.

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2. Mountfort K, Knops R, Sperzel J, Neuzil P. The Promise of Leadless Pacing: Based on Presentations at Nanostim Sponsored Symposium Held at the European Society of Cardiology Congress 2013, Amsterdam, The Netherlands, 2 September 2013. Arrhythm Electrophysiol Rev 2014;3:51-5. doi: 10.15420/aer.2011.3.1. 51.

3. Reddy VY, Exner DV, Cantillon DJ, et al; LEADLESS II Study Investigators. Percutaneous implantation of an entirely intracardiac leadless pacemaker. N Engl J Med 2015;373:1125-1135. doi: 10.1056/NEJMoa 1507192.

4. http://www.massdevice.com/st-jude-calls-global-stop-nanostim-implants-battery-issues/

5. Reynolds D, Duray GZ, Omar R, et al; Micra Transcatheter Pacing Study Group. A leadless intracardiac transcatheter pacing system. N Engl J Med 2016;374:533-541. doi: 10.1056/NEJMoa1511643.

6. Bonner M, Eggen M, Haddad T, Sheldon T, Williams E. Early Performance and Safety of the Micra Transcatheter Pacemaker in Pigs. Pacing Clin Electrophysiol 2015;38:1248-59.

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