The evolution of auto-expandable Portico valve

Resultados y desarrollo de la válvula Portico para el implante percutáneo de válvula aórtica en pacientes con estenosis aórtica severa

Revista Argentina de Cardioangiología Intervencionista 2021;12(4):211-212. https://doi.org/10.30567/RACI/202104/0211-0212

The report by Drs. Fernández-Pereira and associates (1) is an excellent demonstration of what a team of dedicated interventionists can achieve using the Portico valve in the first 40 patients. The success rate, complications of the procedure and results at 15.8 +/- 9.5 months are similar or better than previously published for patients at high risk of surgery or inoperable, see Tables 2 and 3 of the aforementioned article (1). The authors benefited from previous experiences with other implanted valves and previous experience with the Portico valve in other countries and adopted the latest suggestions for a successful implant and optimal results; in this way they were able to overcome some of the learning curve problems observed for most medical devices.

The Portico valve was first used clinically in 2012 (2), and the first 102 patients were published by Monaharan et al in 2016 (3). Since then, several small Registers have been published as shown in **Table 1** and correspond to references 2-8. And more recently a large European registry was published, Portico I (7) and the international randomized clinical trial of Portico vs Sapien/Evolut presented by the Congress of Transcatheter Valve Therapeutics in 2020 and published in the Lancet the same year (9) showing no inferiority to the Sapien and Evolut valves approved by the United States and even greater effective area in the Portico valve compared to the Evolut.

Lately a new release system for the Portico valve was developed, and markedly improved results were published, with greater procedure success, less need for pacemaker, less periprotesic leak and in general better results (10). **Figures 1 A, B and C** describe the new valve release system showing lower incidence of vascular complications determined by the lower profile of the FlexNav **(1D)** release device and better valve implantation with minimal moderate of periprotesic leak **(Figures 2 and 3)**.

More recently, the latest version of the Portico valve, the NAVITOR valve was brought to clinical use and received approval for clinical use in the European Community (CE Mark). This valve has several modifications: an external sleeve designed to avoid perivalvular "leak", a thinner inner sleeve, inward bending of the upper struts and greater radial force, without increasing the delivery profile (14F and 15 F for smaller and larger valves). The results were presented at EuroPCR 2021 by Søndergaard (11) and are described in **Table 2** and **Figure 4**.

Essentially as we see they had no severe grade valve insufficiency after implantation and vascular complications were only 1.2%.

Finally, Abbott has developed a larger Navitor valve, called Titan, that can be used on large valve rings up to 30 mm and clinical studies are underway at this time.

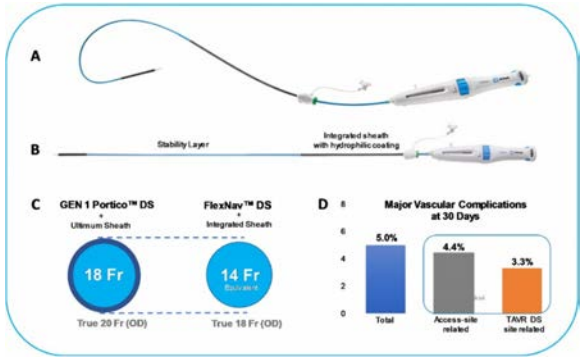

Figure 1. *Nuevo dispositivo de liberación FlexNav de válvula Portico (A, B y C) y disminución de complicaciones vasculares (D).*

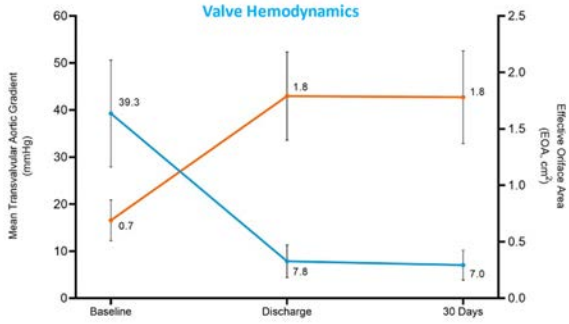

Figure 2. *Área Valvular y gradiente medio de Portico con el nuevo dispositivo de implantación FlexNav inmediatamente después y a 30 dias: significativa mejoría.*

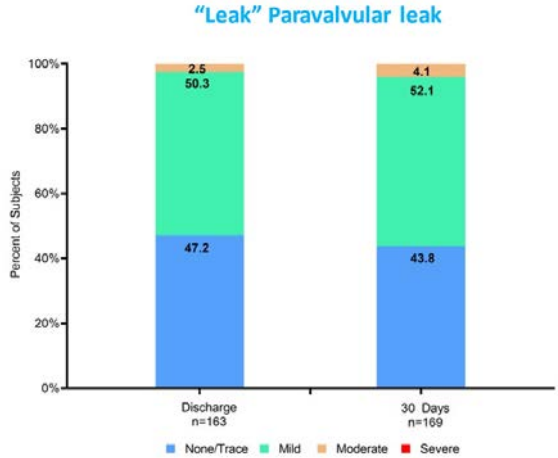

Figura 3. *Leak perivalvular con el nuevo dispositivo de implantación FlexNav. No se observa leak severo 30 días posimplante.*

TABLE 1.

First author	Method	Enrollament period	Sample size	30-day, all-cause mortality	1-year all-cause mortality/survival	Disabling stroke	Major vascular complication	Pacemaker rate	Paravalvular leak
Perlman	Prosp. non rand. MC	2012-14	57	3.5%	Survival: 4.2%	5.3%	8.8%	8.8%	3.6%>mild
Taramasso	Prosp. consecutive SC	2015-16	81	2.4%	-	2.4%	1.2% (4.9% major bleeging)	14.2%	1.2%>mild
Walther	Prosp. non rand. MC	2011-15	198	-	Survival: 92.7% vs. 87.6% sin MCP; NS	-	-	15.2% (30 days) 16.7% (1 year)	-
Linke	Prosp. non rand. MC	2011-15	209	3.6%	Mortality: 13.8%	5.8%	2.4%	14.7%	7.5%>mild
Möllmann	Prosp. no rand. MC	2011-15	222	3.6%	-	3.2%	7.2%	13.5%	5.7% moderate no severe

Prosp.: prospective. Non rand.: nonrandomized. MC: multicenter. SC: single center. NS: not significant.

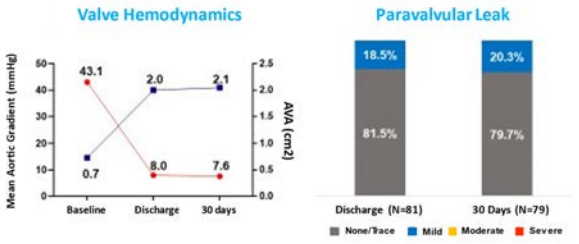

Figure 4. *Resultados a 30 días de la Hemodinamia pos implante válvula NAVITOR. Ausencia de leak moderado o severo. PCR 2021 Presentation by L. Søndergaard.*

TABLA 2. Essential results.

VARC-2 endpoint at 30 days	Navitor (n=83)
All-cause mortality	**0.0%**
Cardiovascular mortality	**0.0%**
Disabling stroke	1.2%
Life-threatening bleeging	2.4%
Acute lidney injury (stage 2/3)	1.2%
Major vascular complication	1.2%
New permanent pacemaker	18.9% *
Moderate or greather paravalvular leak	**0.0%**

**: 11 de los pacintes que requirieron nuevo marcapasos permanentes tenían trastorno de conducción previo. PCR 2021 Presentation by L. Søndergaard. Navitor™.*

In summary, as the authors demonstrate in this publication (1), the Portico valve offers an optimal option for patients with severe aortic stenosis that is being considered for percutaneous implantation. The new designs of both the release system and the Portico valve will facilitate the improvement of the results of the procedure and the clinical results to 30 days and in the remote follow-up.

Augusto Pichard MD
Director Emeritus Cath Labs at Washington Hospital Center, DC.
Former Medical Director Abbott Structural Heart
Professor of Medicine, Georgetown University, Washington DC

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