



Giovanny Ríos D^{1*}, Lina María Marroquín Arias², Juan Rafael Correa³ and William Ríos D⁴

¹M.D, Assistant Professor, Cardiovascular Surgeon, Pontifical Javeriana University, San Ignacio Hospital, Bogota Colombia, Colombia

²Resident of General Surgery, Pontifical Javeriana University, San Ignacio Hospital, Bogota Colombia, Colombia

³M.D, Cardiovascular Surgeon, Head of the Cardiovascular Surgery Program, Pontifical Javeriana University, San Ignacio Hospital, Bogota Colombia, Colombia

⁴M.D, Cardiovascular Surgery, Pontifical Javeriana University, San Ignacio Hospital, Bogota Colombia, Colombia

Received: 29 May, 2019

Accepted: 30 December, 2019

Published: 31 December, 2019

***Corresponding author:** Giovanny Ríos D, M.D, Assistant Professor, Cardiovascular Surgeon, Pontifical Javeriana University, San Ignacio Hospital, Bogota Colombia, Colombia, Carrera 7, Number 40-10, Of: 723, Tel: 2874393; E-mail: edgar.rios@javeriana.edu.co

Keywords: Valvular heart disease; ON-X mechanical prosthetic valves; Functionality; Complications; Anticoagulation; Descriptive study

<https://www.peertechz.com>



Research Article

Demographic, clinical characteristics and results of postoperative follow-up, in patients with valvular cardiopathy handled with ON-X mechanical valves in San Ignacio Hospital between the years 2006-2015-2019

Summary

Overall objective: To describe the demographic, morbidity and indications for valvular heart valve surgery, operated with ON-X mechanical valves at the San Ignacio Hospital between 2006-2015. Describe the experience of the Hospital, the reasons for the surgeries and the evolution of these, with special emphasis on type and level of anticoagulation and complications.

Methods: Descriptive observational study based on the surgical registry of the Cardiovascular Surgery service of San Ignacio Hospital during the years described. From this registry, the information was searched in the medical records of all patients treated at the Hospital during the period between 2006 and 2015, an update to 2019 who received one or two ON-X mechanical valves, either due to an isolated valvular heart disease or for valvulopathy associated with another heart disease, such as ischemic heart disease.

We excluded only incomplete medical records or those in which postoperative follow-up data could not be obtained.

The data are useful to know the HUSI experience with ON-X mechanical valves and to compare, with the necessary precautions for population differences, with other similar institutions in Colombia and in world literature.

Results: A total of 305 patients were taken at aortic or mitral valve exchange and received mechanical On-X prostheses.

There was 30-day mortality in 30 patients given the high morbidity and complexity of procedures. At one year, 6 patients were added to mortality.

Conclusions: The ON-X valves have shown advantages over other valves on the market, related to their structure, which decreases the pannus formation, and the results in relation to the PROACT study increase the interest for this type of valve.

Introduction

Heart valves can be affected congenitally or acquired. According to the speed of establishment of the disease, they give rise to two syndromes, which, although affecting the same structures, behave differently due to the different adaptation of the myocardium. Among these are acute instauration (AMI, endocarditis, thrombosis, aortic dissection, etc.), which is generally poorly tolerated and can quickly lead to heart failure with low pulmonary edema and pulmonary edema.

The therapeutic attitude must be immediate. The other cases are those of chronic instauration, which sets in motion compensatory mechanisms maintaining normal ventricular function until advanced stages [1-4].

The organic valvulopathies usually progress making necessary the valvular substitution by a prosthesis. Functional valve diseases (secondary to dilatation or failure of the valvular apparatus due to another cause) usually improve after treatment of the primary cause.



- a. The stenosis of the exit valves of the ventricles generates resistance to flow, which is compensated by concentric hypertrophy and good ventricular function is maintained until the myocardium claudicates (hypertrophy creates areas with less coronary risk). As a rule, they manifest clinically before ventricular failure, warning the moment when the valvular change will be necessary.
- b. The insufficiencies lead to ventricular dilation due to volume overload (eccentric hypertrophy) that initially compensates, but degenerates into ventricular failure. The fault is usually before the clinic, making it difficult to predict the existence and require closer control. As an interesting fact, the higher volume offered increases the ejection fraction, so that a seemingly normal value of it can already indicate slight dysfunction.
- c. In stenosis of the atrioventricular valves, symptoms occur due to retrograde congestion (pulmonary in mitral stenosis and systemic in tricuspid stenosis), but the ventricles are not affected, since they are protected from this pressure increase [1-4].

The clinic of the valvulopathies can be both anterograde and retrograde. In left lesions, pressure is transmitted to the pulmonary vascular bed (with dyspnea, pulmonary edema). This bed responds by increasing the resistance, which initially protects the pulmonary edema, although later it leads to irreversible organic changes in the pulmonary arterioles with pulmonary hypertension and posterior right fault.

There may be clinical complications in these valvular diseases such as embolisms, endocarditis, arrhythmias and even sudden death.

Regarding valve replacements in general, it is accepted that thromboembolic complications after valve replacement with a biological prosthesis are 0.2-3.8% in the aortic position and 0.3-5.1% in the mitral position [1-4].

Durability is still an advantage of these valves, since up to 90-95% are free of failure at 6-7 years and 70% at 10 years. However, it is necessary to improve these figures.

Patients older than 70 years, or with a life expectancy of less than 10 years and those who can not take anticoagulants due to a history of bleeding, or patients who do not want to take anticoagulants are the most appropriate candidates for a biological valve.

Regarding mechanical valves, the main complication is the effects of anticoagulation. It is accepted that morbidity secondary to hemorrhage is 1-3% per patient per year, and mortality is 0.1-0.5%.

For patients between 60 and 70 years, the selection of the type of prosthesis is usually determined between the patient, the surgeon and the preferences of the center. There is ample current variability, however, in relation to the type of valve that must be implanted or the option to perform plasty.

In our service we have opted for the use of ON-X mechanical valves, basically due to the hemodynamic and durability advantages, for the protection of the discs by a wider support that prevents obstruction by pannus and by the possibility of giving lower doses of warfarin to the patient, and because they need potentially lower anticoagulation values.

The study by Mervyn A. Williams shows the long-term results in a population treated with mechanical ON-X valves and managed with a lower level of anticoagulation in the Riet van Sonia Provincial Hospital, Port Elizabeth, South Africa. Next, the data taken from this important study are shown [4].

The objective of the study was to evaluate the clinical performance of the ON-X cardiac valve in a population of students with socioeconomic disadvantages. The majority of the patients were indigenous, with low educational level, and with multiple geographical locations. Between 1999 and 2004, 530 valves were implanted (242 mitral valves, 104 aortic valves, 92 double valves) in 438 patients (mean age 33 years, range: 3-78 years). The most common reason for the surgery was rheumatic valve disease (57%), followed by degenerative valve disease (11%) and infectious endocarditis (9%). The follow-up was 95% for a total of 746 patients-year (pt-year). Among the patient population, 40% were without anticoagulation or anticoagulated unsatisfactorily. Hospital mortality was 2.3% and none of the deaths in the hospital was related to the valve. The mean (\pm SE) survival (including hospital deaths) at four years was: 73.8 \pm AVR 8.1%, 83.4 \pm MVR 5.7% and 60.9 \pm 10.3 DVR%. Linearized rates (by AVR, MVR and DVR, respectively) for late complications (%/pTyr) were: bleeding episodes 0.6, 1.0 and 2.3; thrombosis 0.0, 0.2 and 0.0; endocarditis 0.6, 1.0 and 2.3; paravalvular leaks 0.6, 0.2, and 0.0; systemic embolism 1.1, 1.5 and 3.5. The majority of systemic embolisms are related to infective endocarditis. Among the patients there were seven pregnancies without full-term complications. As a conclusion of the study, taking into account the erratic coverage of anticoagulation and a high incidence of infective endocarditis, the results of this study can be considered encouraging. The low incidence of valve thrombosis (one case) was remarkable. These data also suggest that the On-X valve can be implanted with relative safety in women who wish to have children. [4].

The enthusiasm after the introduction of mechanical valves during the 1960s was quickly affected by the documentation of a high incidence of thromboembolic complications. Although the use of anticoagulants reduced the incidence of thrombosis and thromboembolism, the problem of hemorrhage related to the anticoagulant was introduced. Consequently, physicians involved in the care of patients with mechanical valves must follow a path between bleeding with anticoagulants and thrombotic complications.

Among the large number of mechanical valves that have been introduced into clinical practice - all of them with the hope that the incidence of valve-related complications will be reduced - few have had long lives and currently only a handful are implanted in a regular. The ON-X two-disc valve was first used clinically in September 1996. The valve is manufactured from On-X carbon, a pyrolytic compound without silicone. The



elimination of silicone from the results of the manufacturing process has resulted in a much milder surface and theoretically lower thrombogenicity. The valve housing has a tubular configuration instead of the configuration of the washer used in other devices. The valve has a flared inlet and a natural ratio of length to diameter. This design, when combined with the full opening prospects, results in linear flow with minimal turbulence. These innovative design features suggest that the On-X heart valve offers advantages over other mechanical valves.

Recently the results of the PROACT study have been received: Reduced Anticoagulation after Mechanical Aortic Valve Replacement Interim results from prospective randomized ON-X Valve anticoagulation Clinical Trial Randomized FDA investigational device exemption trial "Puskas J. Et al" J. Thorac Cardiovasc Surg 2014, Apr, 147 (4: 12002-12010) doi: 10.1016/j.jtcvs.2014.01.004 [5].

- 375 AVR patients: 190 controls and 185 cases.
- September 2006 to 2009.
- Inr 1.5-2.0 after the 3rd month, plus 89 mg of ASA.
- INR: 1.89 +/- 0.49
- Lower bleeding rates.
- The other complications: TIA and total neurological events were similar.

These results of the proact study further support the progressive use of these valves.

Aware of the large population that goes to the Cardiovascular Surgery service, and taking into account the greater survival of the patients, and the current wide discussion about the type of technique and the type of valve selected, it has been decided to describe the panorama of our patients, to have information about the experience, that allows to have an approximate panorama of the clinical situation with the ON-X valves in a university center.

Overall objective

To describe the demographic and morbidity characteristics, as well as the indications, evolution and complications of patients with valvular heart disease to whom one or two ON-X mechanical valves were implanted in the Hospital San Ignacio between the years 2006-2015 an update to 2019.

Specific objectives

- Describe the sociodemographic variables such as sex, age and origin in the operated patients.
- Describe the indications and comorbidity of the operated patients.
- Describe the evolution and morbidity and mortality of patients operated with mechanical ON-X valves.

- Describe the postoperative follow-up, with emphasis on functional status, values of INR obtained, data according to the type of valve (aortic or mitral), complications of anticoagulation and complications with sub-therapeutic levels of INR.
- Describe gradients and echocardiographic function in patients with double mechanical valvular change.

Methods

Definition of the method

It is a descriptive, observational, historical cohort study, based on a registry. We obtained, by review of medical records, data such as type of valvulopathy, sex, age, surgical management and technique, associated injuries, type of complications, functional status and prosthesis status, as well as INR controls and values and the distribution of their values according to whether there were complications or not.

Study population

All patients with valvular heart disease of all ages, of both sexes with all types of valvular disease, who had been operated on with mechanical ON-X valves, in the Cardiovascular Surgery Service of the San Ignacio University Hospital between 2006-2015 an update to 2019.

Inclusion criteria

Patients who underwent surgery at the San Ignacio Hospital with a mechanical ON-X prosthesis for the diagnosis of aortic or mitral valve disease, during the period between January 2006 and March 2015, whether they had entered through the Emergency Department or scheduled by external consultation. that they had a complete medical history for the necessary data.

Exclusion criteria

Impossibility of following the patient by history or by telephone.

Variables: Sex, origin, age, comorbidity, type of valvulopathy and associated diseases, type of surgery performed and location of ON-X mechanical valves, morbidity and mortality of cardiac valvular disease operated with mechanical ON-X valves. postoperative functional status, average of INR managed, INR according to valve, complications of anticoagulation, complications according to therapeutic INR or subtherapeutic levels. Gradients and echocardiographic function in patients with double mechanical valvular change.

Data Collection techniques

Source of information: This is a primary source in a retrospective study based on a registry. The data were obtained from the medical records, and additionally the patients were followed through postoperative controls and telephone follow-up. The data will be obtained by the researcher through the format.



Evaluation format: Data are obtained retrospectively from the Clinical History, with a prospective component of post-surgical follow-up.

Collection of the data: the data will be collected between May 2015 and June of the same year. They will be stored in a database in Microsoft Excel and will be processed, for statistical analysis, in Stata 13 (StataCorp) in the Department of Clinical Epidemiology of the Faculty of Medicine, Pontificia Universidad Javeriana.

Control of Biases and Errors: We are aware of the reference bias, because although the population is heterogeneous, the intrinsic characteristics of patients such as race, cultural level, nutritional status, socioeconomic status, comorbidities can not be controlled and are possibly related to the reasons why Patients consult or are referred to HUSI. The limitation in extrapolability is assumed, since it is primarily a descriptive study in a defined environment. There is no sampling error since it is a study in which all the patients operated on with ON-X prostheses will be selected for the description of the universe. All the valvulopathies have spectrum variability, given by the type of injury, the degree of ventricular involvement, the type of clinical repercussion and the age of presentation, with the time of evolution of this. It may happen that the variability is not well represented by limited sample size, so the descriptive nature of the study is emphasized.

There are risks of random error since the data is taken from the stories, and there may be underreporting. Potentially this would mean bias if one thinks that extreme cases are more likely to be registered, with very good results or with complications, but it is impossible to quantify this risk, as well as to know the direction of the error. This is why it is considered more random error than bias, but it is a clear limitation of the study. We will try to validate and complement the information with the telephone follow-up and in some cases by calling patients with double valvular change for echocardiography.

In the measurement, absolute values recorded in the medical records were used as age-in-years, presence of valvular heart disease, type of injury, valvular change, evolution and complications, as well as data related to anticoagulation and related complications. We will try to minimize errors in data collection since the study will have a single data collector, trained and will do the process systematically.

Analysis plan

For this type of analysis, it is necessary to bear in mind that most of the measures are expressed in frequency as absolute values.

According to the evidence, surgical management behaviors have been taken. The type of mechanical valve does not vary, but if the position of this.

In terms of age, it will be represented on average given that the average will be obtained within a range according to the

findings. Sex will be represented in frequency as an absolute value.

Valvulopathies will be expressed in frequencies, as well as associated injuries.

In the follow-up there may be variability since it is a less objective measurement expressed in the feeling of each patient and in some cases with objective measures according to the clinical history and records of echocardiography and INR.

The study will make standardized and precoded collection of registry information, with subsequent validation in patients who are contacted for echocardiographic evaluation. Potential errors in the registry are assumed as weakness of the study, more likely as a random error than as a bias.

Results

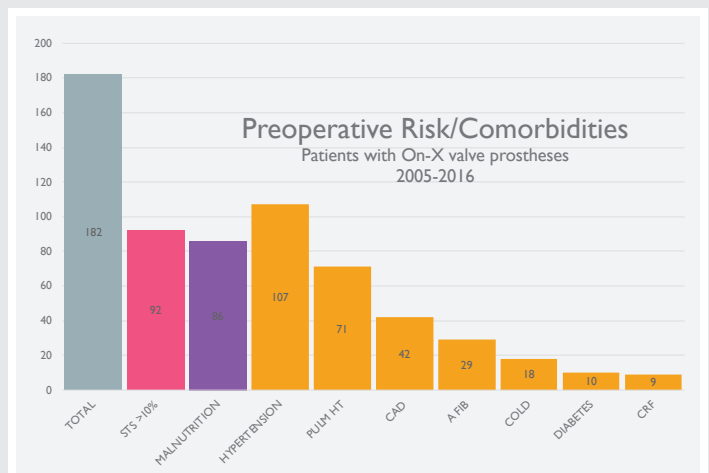
182 patientes 85 women 97 men

Average age 53.8 years.

Distribución por género	Number of patients	Percentage
Women	85	46.7 %
Men	97	53.2%

Origin	Number of patients	Percentage
Bogotá	146	80.21 %
Other city	36	19.7 %

TYPE OF PROCEDURE	n
ISOLATED AVR	70
ISOLATED MVR	34
AORTIC VALVE REPLACEMENT + CABG	15
MITRAL VALVE REPLACEMENT + CABG	16
AVR+ASCENDING AORTA REPLACEMENT	12
AVR+MVR	15
MVR+TRICUSPID ANNULOPLASTY	18
MVR+TVR	2





Surgical technique

AORTIC

1. Thorough decalcification
2. Meticulous accurate annular sizing
3. Multiple evenly distanced simple non/pledget stitching in most, definitely in 19-21mm annuli

MITRAL

1. Conventional mutiple atrial sided pledgeted "U" stitching

DOUBLE VALVE

1. Aortic first-in: with mitral anterior leaflet stitches in place
2. Favor simple stitiching for AVR

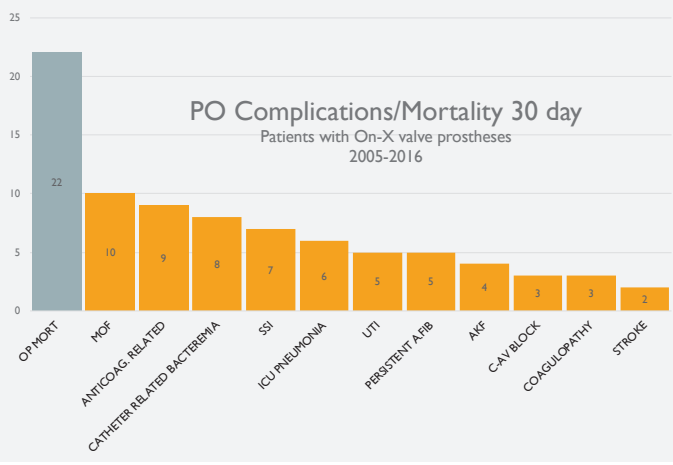
Anticoagulation scheme

WARFARIN

- Aortic/Mitral: INR 2.5 - 3.5
 Double Ao/Mi: INR 3.0 - 3.5

AFTER PROACT

- Subset of Aortic 28 patients on reduced warfarin (RAC) INR 1.5 - 2.0 + ASA100 mg/day *
 23 low risk aortic valve started on RAC at 3rd PO month
 5 Low risk patients converted to RAC after at least 16 months on regular scheme



Follow up summary

MORTALITY	n	%
Operative, 30 day	22	12.8
1 year	3	14.4
5 year	4	16.6

OUTCOME	n	%
Hemorrhagic Stroke	3	1.7
Ischemic Stroke/Thrombolysis	3	1.7
Thrombosis, device*	0	0

INR out of range (> 3 episodes/last year)	163	93
VKA therapy abandonment > 2 weeks	34	19
Recurrent epistaxis	5	2.8
Pericardial effusion/Drainage	4	2.2
Severe GI tract bleeding	6	3.4

OUTCOME	n	%
Reoperation / PO bleeding	17	9.3
AV block / pacemaker	2	1.1
Major Operative Site Infection	3	1.7
Patients under 15 y-o	3	1.6
Perivalvular leak	3	1.6
Postop Endocarditis	1	

2019 update

TYPE OF PROCEDURE	2006-2015	2016	2017	2018	2019	Total
ISOLATED AVR	70	16	15	15	3	119
ISOLATED MVR	34	10	11	5	3	63
AORTIC VALVE REPLACEMENT + CABG	15	2		1		18
MITRAL VALVE REPLACEMENT + CABG	16	2	2	1		21
AVR + ASCENDING AORTA REPLACEMENT	12	3	5	6	3	29
AVR + MVRa	15	4	5	2	4	30
MVR + TRICUSPID ANNULOPLASTY	18	1	2	2		23
MVR + TVR	2					2
Σ	182	38	40	32	13	305

Future developments

RESEARCH

1. Outcomes in Valve Surgery: Defining standards for population specific needs and health system possibilities.
2. Outcomes in RAC related to our population characteristics.

QUALITY CARE

1. Improve preoperative patient comditions.
2. Improve follow up and postoperative care resources.

Conclusions

- The ON-X valves have shown advantages over other valves on the market, related to their structure, which decreases the pannus formation, and the results in relation to the PROACT study increase the interest for this type of valve.
- In our service for 10 years we have used this valve, becoming the service of the whole country that has more valves of this generation.
- The results are encouraging in relation to minor complications of the valve such as disc obstruction, thrombogenicity and ecv secondary to sobreanticoagulation or sub anticoagulation.



- Cardiac function measured by clinical and echocardiography was preserved.
- We have not registered acute obstruction due to thrombi of any of our prostheses.
- Mortality remains within the expected ranges, being general 8.6%.
- This includes mitral valves, and combined mitral procedures with coronaries, aortic valve with coronary arteries and procedures in the ascending aorta.
- We intervened 3 children in whom this prosthesis was implanted with an adequate result, without thrombotic complications.
- The advantages of these prostheses, described in the Proact study, added to the population that we intervene (patients from Bogotá and national territories), in which follow-up is difficult, adherence to anticoagulation, monitoring and administration of medication by the EPS are not reliable and the possibility of enrolling with subtherapeutic is higher, indicating that the prostheses have given good results with fewer complications to which the literature refers in mechanical prostheses.

References

1. Kouchoukos Nicholas T, Eugene B, Donald D (2003) Cardiac Surgery, Kirklin / Barratt Boyes, Third Edition. Acquired Valvular Disease. Cap 11-15. Elsevier Science. American Association for Thoracic Surgery, Seminars in Thoracic and Cardiovascular Surgery.
2. Cohn (2004) Cardiac Surgery, Acquired and Congenital Valvular Disease. Sociedad Colombiana de Cardiología y Cirugía Cardiovascular. Enfermedad Valvular Cardíaca. Edit. Colina.
3. Lee R, Li S, Rankin JS, O'Brien SM, Gammie JS, et al. (2011) Fifteen-year outcome trends for valve surgery in North America. Society of Thoracic Surgeons Adult Cardiac Surgical Database. Source, Northwestern University Medical Center, Chicago, Illinois, USA. Annals Thoracic Surgery 91: 677-684. [Link: http://bit.ly/2F449hs](http://bit.ly/2F449hs)
4. Williams MA, van Riet S (2006) The On-X heart valve: mid-term results in a poorly anticoagulated population. J Heart Valve Dis 15: 80-86. [Link: http://bit.ly/37p9TP0](http://bit.ly/37p9TP0)
5. Puskas J, Gerdisch M, Nichols D, Quinn R, Anderson C, et al. (2014) Reduced anticoagulation after mechanical aortic valve replacement: Interim results from the Prospective Randomized On-X Valve Anticoagulation Clinical Trial randomized Food and Drug Administration investigational device exemption trial. J Thoracic Cardiothorac Surg. 147: 1202-1211. [Link: http://bit.ly/354JYuk](http://bit.ly/354JYuk)

Discover a bigger Impact and Visibility of your article publication with Peertechz Publications

Highlights

- ❖ Signatory publisher of ORCID
- ❖ Signatory Publisher of DORA (San Francisco Declaration on Research Assessment)
- ❖ Articles archived in worlds' renowned service providers such as Portico, CNKI, AGRIS, TDNet, Base (Bielefeld University Library), CrossRef, Scilit, J-Gate etc.
- ❖ Journals indexed in ICMJE, SHERPA/ROMEO, Google Scholar etc.
- ❖ OAI-PMH (Open Archives Initiative Protocol for Metadata Harvesting)
- ❖ Dedicated Editorial Board for every journal
- ❖ Accurate and rapid peer-review process
- ❖ Increased citations of published articles through promotions
- ❖ Reduced timeline for article publication

Submit your articles and experience a new surge in publication services (<https://www.peertechz.com/submit>).

Peertechz journals wishes everlasting success in your every endeavours.

Copyright: © 2019 Giovanni Ríos D, et al. This is an open-access article distributed under the terms of the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original author and source are credited.

Citation: Giovanni Ríos D, Marroquín Arias LM, Correa JR, William Rios D (2019) Demographic, clinical characteristics and results of postoperative follow-up, in patients with valvular cardiopathy handled with ON-X mechanical valves in San Ignacio Hospital between the years 2006-2015-2019. Int J Vasc Surg Med 5(1): 014-019. DOI: <https://dx.doi.org/10.17352/2455-5452.000035>