Bentall - De Bono Operation with a Biological Valved Conduit (INSTAR®)

AUTHOR'S LIST

1. Sergio Figueiredo Campos-Christo, PhD (1)
2. Sergio Almeida Oliveira, PhD (2)
3. Geraldo Paulino Santana-Filho, MD (3)
4. Genivaldo Coelho Souza, MD (4)
5. Jose Carone Jr., MD (5)
6. Januario Manoel de Souza, MD (2)

(1) Felicio Rocho Hospital, Belo Horizonte, Brazil

(2) Beneficencia Portuguesa, Sao Paulo, Brazil

(3) Santa Casa de Misericordia, Goiania, Brazil

(4) Pio XII Hospital, Sao Jose dos Campos, Brazil

(5) Evangelico Hospital, Vitoria, Brazil

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- Aortic valve
- Aortic aneurysm, thoracic
- Bioprosthesis
- Valve graft composite

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INTRODUCTION

Since the publication of Bentall and De Bonno[1], we have seen a remarkably successful progression on surgical treatment of root and ascending aorta aneurysm, and improvements, in the operative technique, resulted in low operative mortality [2,3,4]. The increasing number of elderly patients with aortic valve and ascending aorta diseases, compelled new research looking for an ideal biological valved conduit. The INSTAR® biological stented valved conduit is an option to be used in Bentall procedure, specifically in patients in whom anticoagulation is not recommended or is contraindicated.

INSTAR® BIOLOGICAL STENTED VALVED CONDUIT

The INSTAR® conduit is composed of a stented pericardial aortic valve (Labcor Model P2010 – *Belo Horizonte, Brazil*), sutured to a polyester vascular ultra-low porosity "woven" prosthesis, blood-sealed without any coating. The length of the conduit is appropriated to the replacement of the entire ascending aorta. It also has an enlarged suture ring that enables two suture rows. This technique allows better coaptation between valved conduit and aortic ring, preventing blood leakage.

The INSTAR® biological stented valved conduit is stored in glutaraldehyde solution, is ready-to-use after a thorough soak in saline solution and is available in many sizes (fig.1).

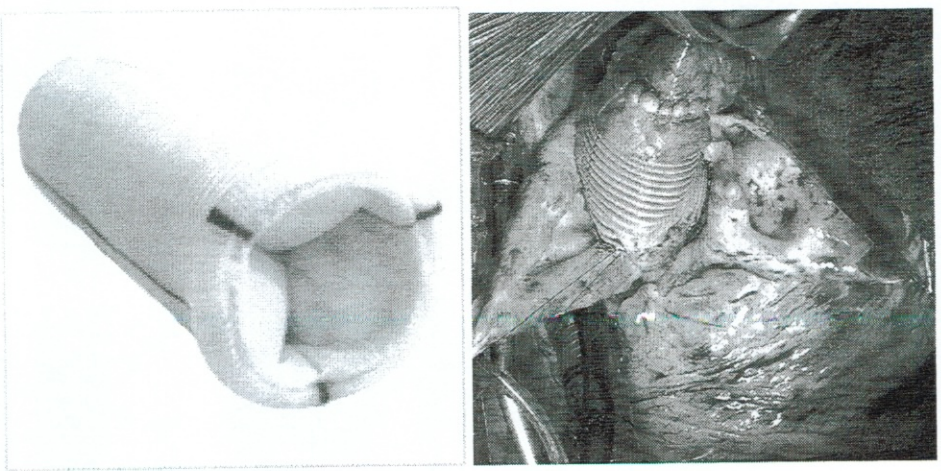

Fig.1 – External and implanted view of INSTAR®

OBJECTIVES:

- To observe the implantability, hemostatic properties and surgical handling of INSTAR®, in modified Bentall operation;
- To check "hospital-stay" and early postoperative term outcomes of INSTAR®.

METHODS

The records of 28 subsequent patients submitted to modified Bentall-De Bonno procedure using INSTAR® Composite Prosthesis, from October 2008 to May 2010, in selected surgical teams, were reviewed in order to determine the implantability, haemostatic characteristics, and early postoperative results. Patient consent was waived.

A survey focusing surgical handling and implantability characteristics was applied to all surgeons involved in the implantation of INSTAR® in Bentall procedure.

CLINICAL EXPERIENCE

- Demographics

From October 2008 to May 2010, 28 patients (18 males and 10 females) were submitted to modified Bentall procedure in selected institutions. There was a higher prevalence of aortic degenerative diseases in the sample studied, with the most prevalent age group, (23 patients) distributed among middle-aged and aged people (median: 63,5 years). In only four patients (14,3% of the sample) the operative procedure took an emergency character (type A acute aortic dissection). Aortic insufficiency was found in the great majority of patients (26 patients). Coronary artery disease and mitral valve regurgitation were associated to aortic root disease in 4 patients, respectively. In 2 patients, the asceding Aorta aneurysm reached the aortic arch (table 1).

Table 1 – Demographics of Patients

Variables	**Mean SD (range)**
Age, (year)	58,6 ± 13,2 (28-77)
Sex	
Male	18
Female	10
Aortic Root Disease	
Degenerative root aneurysm	21
Acute Dissection (type A)	4
Ascending and Arch aneurysm	2
Aortic Prosthesis disfunction / Aorta laceration	1
Aortic Stenosis	2
Aortic Insufficiency	26
Coronary artery diseases	4
Mitral valve insufficiency	4

- Surgery

Modified Bentall operation was performed in all patients (fig.2). Three patients had been submitted to previous cardiac surgery (redo operations). Coronary artery bypass grafting and mitral valve replacement, were performed in 4 patients, respectively. Total circulatory arrest was applied in 12 patients with high ascending aorta aneurysms, total arch replacement and aortic dissection.

RESULTS

During hospital-stay there wasn't any death nor excessive post-operative bleeding rethoracotomy. The mean cardiopulmonary bypass and cross-clamping times were in acceptable ranges (table 2). During post-operatory follow-up time (mean: 9,6 months) there were no INSTAR® conduit related reoperations.

In the surgical-handling /implantability characteristics' survey, all surgeons confirmed the easy handling and hemostatic properties of the device.

Table 2 – Operative Data

Variables	**Mean SD**
CPB duration (min)	123 ± 44
Aortic cross-clamp (min)	93 ± 42
Circulatory arrest (min) / 12 patients	11 ± 3
Concomitant Procedures	
CABG	4
Mitral valve replacement	4
Aortic arch replacement	2

DISCUSSION

The degenerative aortic diseases accounted for 13.328 deaths in 2006, in the USA[4]. The aortic valve, root and ascending aorta composite replacement with mechanical-valved conduit is the "gold standard" surgical treatment to diseases simultaneously affecting these anatomical structures. Although improvements in materials [5] and modifications in surgical technique [2,6,7] resulted in excellent rates of survival and long term durability, the persistent anticoagulation, associated to the aortic mechanical prosthesis, raises the risk of thromboembolic and hemorrhagic complications, particularly in older people and patients with other aortic affected segments (*e.g.*: type B aortic dissection/ thoracoabdominal aneurysm) [8,9,10]

Pulmonary autografts ("Ross operation") and aortic allografts shared a lot of contraindications[11] (*e.g.*: severe ventricular dysfunction, severe coronary artery disease, aortic annulus >30mm, multiple valve disease requiring replacement, Marfan syndrome and concomitant immune-mediated diseases), as substitutes in Bentall operation. The valve-sparing procedures proposed by David[12,13] and Yacoub[14] are promising, but they are not always applicable, are technically complex and demands specific training.

The improvements observed in new generation biological valves, with longer durability, coupled with the aging of population, expanded the use of the biological valved conduits[15].

The former composite biological valved conduit consisted of a stented glutaraldehyde tissue prosthesis "handsewn intraoperatively" to a impregnated Dacron tube[15]. Biological stentless aortic valve, were also intraoperatively sutured to a vascular graft [16,17] in Bentall operation. Both procedures carry the potential risk of lengthening aortic cross-clamp and cardiac ischemia times. Moreover, this "hand-maid" conduit isn't submitted to quality control protocol, thus increasing the risk of unrecognized prosthetic dysfunction.

The xenograft valved conduits don't require intraoperative assembly. On the other hand, they aren't long enough to substitute all the ascending aorta and are prone to calcification. The complexity of the replacement of the wholeness of a degenerated xenograft valved conduit imposes additional risk to the patient [18]. The composite bioprosthesis valved (stented / stentless)

xenopericardial conduit[19] also features the risk of degeneration of its tissue components (bioprosthesis and xenopericardial vascular graft), demanding as well, complex and risky redo operations.

Recently, prepacked biological valved conduits, composed of vascular impermeable to blood graft and pericardial / porcine stentless aortic valve became available. This kind of device exempts the assembly of the aortic valved conduit in the operating room [20].

The INSTAR® biological valved conduit constitutes an anticoagulation-exempted, ready-to-use option in Bentall operation. The results of this early experience, without any bleeding requiring rethoracotomy, and no death related to INSTAR® in 9,6 months mean follow-up are encouraging and warrant further experience.

CONCLUSIONS

- INSTAR® represents a new pre-assembled composite prosthesis that offers easy surgical handling and hemostatic attribute, associated to practical advantages of a ready-to-use device and anticoagulation exemption.
- The initial results obtained in this series confirm the efficacy of this new device and places INSTAR® as an option that should be considered in Bentall procedure.

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