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Starr Edwards Prosthesis in Aortic Position: What is the Outcome After 40 Years without Anticoagulation?

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SUMMARY:

For more than sixty years, the use of valve prostheses in the management of valvular heart diseases has seen significant growth. The existence of two types of prostheses, mechanical and biological, combined with clinical data directly related to the patient, has led surgeons to define selection criteria. More than 280,000 valve prostheses are implanted worldwide, half of which are mechanical prostheses. All valve prostheses, regardless of their type and size, present a certain degree of obstruction compared to the native valve, quantified by transthoracic echocardiography, based on the permeability index (PI) and the effective valve area (EVA). The main organic causes of obstruction are: prosthetic thrombosis, especially in mechanical prostheses, infectious endocarditis, calcific degeneration of biological prostheses, and, more rarely, fibrous pannus.

KEYWORDS: Biological and mechanical prostheses - Starr Edwards prosthesis - Cardiac imaging - Surgical resection

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FIGURE LEGEND:

Figure 1 : Different types of prostheses

Figure 2 : National and international recommendations for anticoagulant chemoprophylaxis in patients with valve prostheses.

Figure 3 : Starr Edwards prosthesis of our patient after surgery.

Figure 4 : Evolution of mechanical prostheses.

INTRODUCTION:

Valvulopathies encompass all conditions affecting the heart valves of various etiologies. Since 1952, when the first valvuloplasty was performed by Dr. Charles Hufnagel, the treatment of these pathologies through the replacement of the native valve has continuously progressed, mainly due to improvements in the proposed valve prostheses and surgical techniques. Thus, in 2004, approximately 250,000 patients worldwide underwent this type of intervention. Two families of valve prostheses coexist and share the market: mechanical prostheses and biological prostheses ('bioprostheses'). In this article, we will focus primarily on the description of the Starr-Edwards ball prosthesis as well as the management of thrombosis risks.

CLINICAL CASE:

A 61-year-old patient of Moroccan origin, with cardiovascular risk factors including chronic smoking at a rate of 30 pack-years, dyslipidemia under statin treatment, and a history of aortic valve replacement in 1982 abroad in France, likely related to infectious endocarditis with a ball prosthesis. He was initially placed on anticoagulants, which the patient has not taken for the past 40 years. He was admitted for the management of worsening dyspnea over the past year, progressing from NYHA class III to IV.

Our patient underwent an urgent echocardiogram which revealed a mechanical ball prosthesis in the aortic position, likely stenotic, with a maximum aortic velocity of 4.89 m/s, a mean gradient of 51 mmHg, a Doppler velocity index of 24%, a cross-sectional area of 0.55 cm², and a time-accelerated contraction of 114 ms. The left ventricle showed good global and segmental kinetics, with preserved left ventricular function and a left ventricular ejection fraction of 57%, associated with minimal tricuspid and mitral regurgitation and an intermediate probability of pulmonary hypertension.

We followed up with a trans esophageal echocardiogram, which confirmed the mechanical prosthesis in the aortic position, a Starr cage type with preserved ball mobility, without visualization of a thrombus or any suspicious elements.

The patient was presented to the surgeons, and after preparation, he underwent a double leaflet aortic valve replacement with a Saint Jude Medical prosthesis, with a normal control echocardiogram afterward.

DISCUSSION:

1- History and evolution of prostheses [4] (Figure 1)

Mechanical valves were the first to be used. The oldest is the Starr Edwards® ball prosthesis, which dates back to 1960 [6]. Since that time, extensive research has been conducted to improve the performance of valve prostheses in terms of materials, whether synthetic or biological, as well as in the fields of hydrodynamics and fluid flow.

- **Mechanical Prostheses**

Three generations of mechanical prostheses have succeeded each other:

- 1st generation: "ball" type; This includes the Starr Edwards® from 1960;
- 2nd generation: "tilting disc" or "mono-leaflet." The leader of this generation is the Björk-Shiley® introduced in 1969;
- 3rd generation: "bileaflet." The first model was the valve from Saint Jude Medical in 1977.

As of 2005, ball mechanical prostheses are of purely historical interest but are still marketed.

- **Bio prostheses**

Biological valves are either homograft or more frequently heterograft.

- Heterograft or bio prostheses are made from animal tissue (pig valves or calf pericardium) and undergo a glutaraldehyde preservation process that maintains their structure while eliminating any viability. There are mainly reinforced porcine bio prostheses and less frequently stentless ones. They are low in thrombogenicity and do not require long-term anticoagulant treatment in most cases, but their gradual deterioration is inevitable and requires re intervention after 10 to 15 years. Bio prostheses are therefore indicated for patients over 70 years old and/or with a life expectancy of less than 10 or 15 years and/or who have a contraindication to anticoagulant treatment.
- Homograft are made from human valves taken from organ donors whose hearts are not used or from heart recipients whose valves are normal. They are sterilized with antibiotics, cryopreserved, and stored indefinitely in tissue banks. Their hemodynamics are perfect, and their degeneration is slow. Additionally, they have excellent resistance to infections and are therefore recommended in cases of endocarditis.

- **Starr Edwards ball valve prosthesis**

After research conducted as early as 1946 to address aortic insufficiency, Hufnagel performed the first human implantation of a ball valve in a heterotopic position in the descending thoracic aorta in 1952, in a patient with aortic insufficiency. The development of extracorporeal circulation techniques allowed for the replacement of heart valves. The first mitral valve replacement was performed in March 1960 by Braun Wald (using a polyurethane valve). The first clinical successes occurred later that same year with mechanical ball prostheses, by Harken in Boston (aortic position) and by Albert Starr (mitral position). The Starr-Edwards ball prosthesis became the reference prosthesis during the 1960s and 1970s. Alongside the implantation of mechanical prostheses, the use of biological tissues was also developed. As early as 1962, Ross developed the use of fresh human homograft in England, followed by preserved ones. Almost simultaneously, Barratt-Boyes advanced this technology in New Zealand. However, due to supply difficulties, extensive research was conducted to use various types of tissues (fascia lata, dura mater, and pericardium). Rapid failures, largely related to tissue trauma during the preparation of biological tissues, led to the temporary abandonment (for the pericardium) of these substitutes. The work done by Carpentier on porcine valves allowed for the first implantation of a heterograft in 1965 by Binet and Carpentier. Development continued

with the establishment of new conditioning methods for aortic valves harvested from pigs: standardization of harvesting and sterilization techniques, and the use of glutaraldehyde (which significantly improved the durability of biomaterials initially treated with formaldehyde).

2- Criteria for the selection of valve prostheses

A valve prosthesis should possess the following properties [11]:

- Non-thrombogenic and non-immunogenic;
- Hemodynamics comparable to a healthy native valve;
- Simple implantation and possible supra- and infra-annular;
- Resistant to infections;
- Easy availability (unlike homografts);
- Silent;
- Significant durability.

3- Aortic valve diseases: context and management [12-13]:

Valvular diseases primarily involve the aortic and mitral valves. The main etiology is dominated by rheumatic fever, which is the leading cause of these conditions in industrialized countries and is rapidly disappearing in developing countries. At the same time, the aging population is leading to an increase in the incidence of valvular diseases, with a progression of mixed valvular lesions (valvular and arterial).

Valvular diseases are often well tolerated for many years. The first functional sign is progressively worsening exertional dyspnea, associated with fatigue and a reduction in walking distance.

It is important to distinguish between aortic stenosis and aortic regurgitation. Currently, three types of lesions are indicated for valve replacement.

- ***Aortic bicuspid:*** accounting for 40% of the etiologies, it is most often the result of a complete fusion between the two coronary cusps, forming a large fibro-calcific ridge extending from the aortic wall to the center of the orifice. The other two commissures, anterior and posterior, are generally intact, resulting in the orifice being reduced to a rigid-edged antero posterior slit, leading to a tight narrowing. The origin of this bicuspid condition is a topic of much discussion. It is often difficult, given the massive nature of the calcification, to determine whether it is congenital or acquired (post-rheumatic). Today, congenital etiology is implicated in 4 out of 5 patients.
- ***Rheumatic aortic stenosis***: accounting for 15% of the etiologies, this condition is related to a history of rheumatic fever, although the certainty is not absolute since the stenosis manifests 40 to 50 years after the initial inflammatory event. The trileaflet architecture of the valve is preserved, but the three commissures and the adjacent valvular segments of the cusps are fused. The orifice can thus reach a diameter of 7 to 8 mm, while the orifice of a normal adult measures 22 to 28 mm in diameter. Most often, the commissural fusion is incomplete, but fibrous and retractive lesions alter the geometry of the cusps, so that significant regurgitation is often associated with the stenosis. Concomitant mitral involvement is common in this etiology.
- ***Aortic regurgitation:*** In rheumatic fever, the aortic cusps are thickened, rigid, with retractions at the free edge leading to a coaptation defect. This condition can later evolve with the appearance of rheumatic aortic stenosis, which causes a certain degree of associated stenosis. The two lesions define aortic disease. Additionally, dystrophic lesions of the ascending aorta should be considered within the context of general dystrophies (Marfan syndrome, Ehlers-Danlos syndrome) or localized dystrophies of the ascending aorta (annuloectatic disease).
- ***Infective endocarditis:*** This etiology leads to two types of valvular involvement:

– Proliferative lesions: vegetations formed of fibrinous tissue containing microbial and leukocyte aggregates, often friable and prone to embolism;

– Mutilations of the valvular tissues with punch-like perforation in the center of the valve or a tear of the free edge or commissural attachment. These lesions are responsible for the abrupt progression observed during infective endocarditis.

- Other, much rarer etiologies include aortic dissections, trauma, and aortitis.

4- Monitoring of valve prostheses

After the implantation of a valve prosthesis, monitoring should begin in the first week post-surgery and continue for life. Echocardiography is the preferred method for following these prostheses [14], one week after surgery and then one month later, noting all the parameters necessary for the subsequent monitoring of the patient and their prosthesis: prosthesis identification card, brand, type, size.

Monitoring parameters for a valve prosthesis (Figure 2)

- **Biological parameters**: anticoagulant prophylaxis involves daily oral intake of an anticoagulant and primarily concerns patients with mechanical valves, as these present a higher thromboembolic risk compared to bio prostheses. A meta-analysis has confirmed the importance of this

anticoagulation [15]. This anticoagulant treatment is indeed necessary to reduce the thromboembolic risk, but it also carries hemorrhagic risks when anticoagulation is excessive. The level of anticoagulation depends on the type of prosthesis, its position (mitral or aortic), the presence of associated atrial fibrillation, and the individual thromboembolic risk. The International Normalized Ratio (INR) is the cornerstone for monitoring the treatment.

- **Echocardiographic parameters** that should be included in the echocardiography report are:
  - Effective orifice area;
  - Mean and maximum gradients
  - Maximum trans prosthetic velocity
  - Calculation of the effective valve area [16] by measuring the effective orifice area
  - Permeability index
  - Presence of valvular regurgitation and its physiological or pathological nature
  - Dimensions of the left and right ventricles
  - Left ventricular ejection fraction
  - Right ventricular function (DTI wave, TAPSE)
  - Right pulmonary pressures and the presence of pericardial effusion.

5- Complications

- **Thrombosis of valve prostheses:** A major complication of mechanical prostheses [17-18]. They are favored by hemodynamic and hemostatic factors. Insufficient anticoagulant treatment is often implicated despite patient education efforts related to poor therapeutic adherence, dietary changes, and drug interactions. The therapeutic management of prosthetic thrombosis has greatly benefited from investigative techniques (first-line transthoracic echocardiography and valve radiocinema, second-line transesophageal echocardiography) that allow for increasingly precise diagnosis (presence, size, mobility of the thrombus, complete or partial blockage of the moving elements of the prosthesis).
- **Prosthetic dislocation:** It is important to distinguish prosthetic dislocation from small paravalvular leaks that are typically observed in the early postoperative period, before complete healing of the ring. Prosthetic dislocation is more common in the first few months after surgery and may be related to the loosening of one or more sutures on fragile tissues (ring calcification, elderly patients), or secondary to endocarditis. The prognosis depends on the etiology, the severity of the leak, and any potential mechanical hemolysis. The severity of the leak is assessed based on clinical signs (dyspnea, pulmonary sub-edema, right-sided signs) and complementary examinations, particularly echocardiography. Transthoracic echocardiography allows for the assessment of the impact of the leak on cardiac chambers and pulmonary pressures; transesophageal echocardiography is essential to specify the severity of the lesions [19-20].
- **Prosthetic endocarditis:** This is the most formidable complication of valve replacement. Infection of the implanted material affects 3 to 6% of patients with a valve prosthesis [21], with an annual incidence of 0.1 to 2% per year, presenting two clinical and bacteriological profiles: early and late prosthetic endocarditis. Early endocarditis typically occurs within 2 months following surgery and is the result of perioperative contamination [22]. The most frequently involved pathogens are staphylococci and Gram-negative bacteria. Late endocarditis occurs more than 60 days after the procedure. Their clinical and bacteriological profile is similar to that of endocarditis on native valves, with streptococci being the most frequently implicated pathogens [23].

As with any endocarditis, the diagnosis of prosthetic endocarditis largely relies on the results of blood cultures and echocardiography, and has particularly benefited from the contribution of transesophageal echocardiography, especially for diagnosing periprosthetic abscesses, which have a dire prognosis with a mortality rate of 30 to 80% in early forms, and 20 to 40% in late forms [21]. Medical treatment should always be employed and includes appropriate, prolonged parenteral antibiotic therapy, generally lasting 6 weeks; accompanied by regular clinical, biological, and echocardiographic monitoring [24]. Surgical treatment consists of replacing the prosthesis along with the complete excision of all infected tissues.

CONCLUSION:

This case offers a rare and valuable perspective on the long-term performance of the Starr-Edwards ball-and-cage prosthesis in the aortic position, functioning optimally for over four decades without anticoagulation. While this outcome may be considered exceptional and not representative of standard care, it underscores the remarkable durability and mechanical resilience of early-generation prosthetic heart valves.

The absence of thromboembolic or hemorrhagic complications over such an extended period, despite the lack of anticoagulation therapy, challenges established assumptions and highlights the potential importance of patient-specific factors, including low thrombogenic risk profiles and favorable

hemodynamic conditions. Nevertheless, it is crucial to reiterate that current international guidelines strongly recommend lifelong anticoagulation in patients with mechanical heart valves to prevent potentially fatal complications.

This case should not be interpreted as a basis to modify current practice but rather as an opportunity to reflect on the complexity of anticoagulation management and the potential role of individualized therapy. Further studies are needed to better stratify thrombotic risk in patients with mechanical prostheses and to explore whether certain subgroups might benefit from tailored anticoagulation approaches in the future.

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ILLUSTRATION:

Prothèses mécaniques		Prothèses biologiques	
À bille	Starr Edwards (1960) Smeloff Cutter	**Porc**	Bioimplant SJM (ex Liotta) Carpentier Edwards Hancock Intact Medtronic Xenomedica Biocor Angell-Shiley Wessex ...
À disque unique	Bjork-Shiley (1969) Lillehei-Kaster (1970) Omni Science (1978) Medtronic-Hall Omni-carbon Sorin Allcarbon	**Péricarde bœuf**	Sorin Pericarbon Ionescu-Shiley Edwards pericardiques Mitroflow ...
À 2 ailettes	Saint-Jude (1977) Carbomedics Edwards- Duromedics Sorin Bicarbon Edwards-Tekna Edwards Mira Medtronic ...	**Bioprothèses sans support**	Edwards Prima Stentless Medtronic Freestyle Toronto SPV

Figure 1: Different types of prostheses

	ESC *European Society of Cardiology* 1995	*SFC* *Société Française de Cardiologie* 1997	*ACC/AHA* *American College of Cardiology / American Heart Association* 1998	*ACCP* *American College of Chest Physician* 2001 et 2004
Prothèses mécaniques mitrales				
– Bille ou disque	3-4,5	3-4,5	2,5-3,5	2,5-3,5
– Double ailettes	3-3,5	3-4,5	2,5-3,5	2,5-3,5
Prothèses mécaniques aortiques				
– Bille ou disque	3-4,5	3-4,5	2,5-3,5	2,5-3,5
– Fibrillation auriculaire[a]	3-4,5	3-4,5	2,5-3,5	2,5-3,5 ou 2-3 + 80-100 mg AAS [c]
– Double ailettes	2,5-3	2-3	2-3[b]	2-3
Prothèses biologiques				
– 3 premiers mois	2-3	2-3	2-3	2-3
Au-delà :				
– rythme sinusal	–	–	80 à 100 mg AAS [c]	80 mg AAS[c]
– fibrillation auriculaire	2-3	3-4,5	2-3,5	2-3

[a] *et autres facteurs de risque thrombo-embolique*
[b] *sauf 3 premiers mois INR 2,5-3,5*
[c] *Acide acétylsalicylique, aspirine*

Figure 2: National and international recommendations for anticoagulant chemoprophylaxis in patients with valve prostheses (according to Hanania et al. [25])

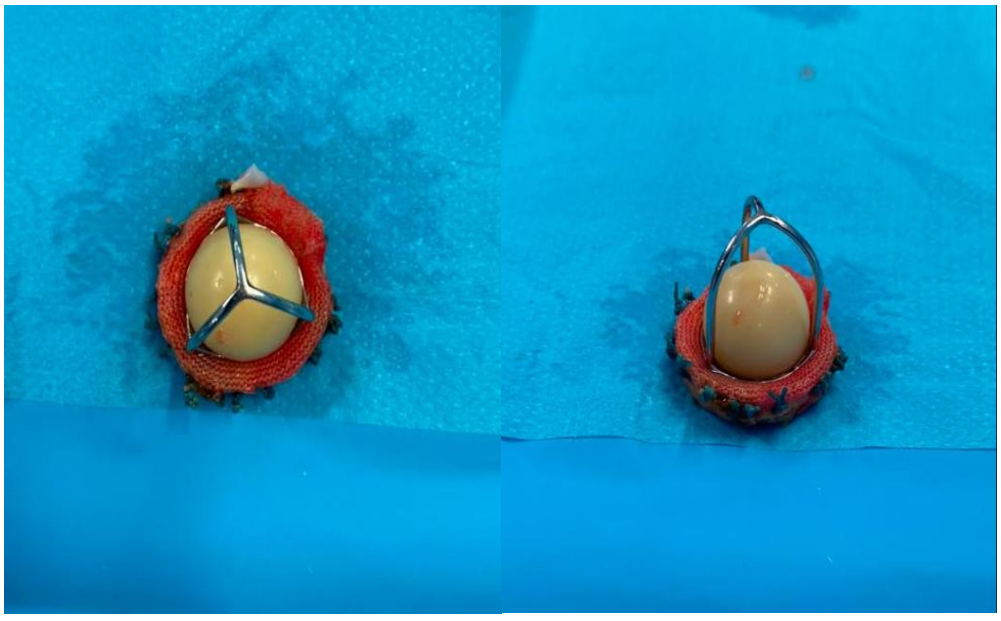

Figure 3: Starr Edwards prosthesis of our patient after surgery.

Figure 4: Evolution of mechanical prostheses: A. Ball valve (Starr-Edwards 6120); B. Tilting disc valve (Björk-Shiley convex-concave model); C. Leaflet valve (Saint Jude Medical)

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Author contribution:

MB: Study concept, Data collection, Data analysis, writing the paper.

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RF: Study concept, Data analysis, writing the paper.

NM: Supervision and data validation

IA: Supervision and data validation

AB: Supervision and data validation

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