EUROPEAN JOURNAL OF
CARDIO-THORACIC
SURGERY

Post operative assessment of a bioprosthetic aortic valve (Labcor)

Torkel Åberg, Xu Yu Jin and Phillip Deverall

Eur J Cardiothorac Surg 2001;20:658-

ELSEVIER

European Journal of Cardio-thoracic Surgery 20 (2001) 658

EUROPEAN JOURNAL OF CARDIO-THORACIC SURGERY

www.elsevier.com/locate/ejcts

Letter to the Editor

Post operative assessment of a bioprosthetic aortic valve (Labcor)

Torkel Åberg[a], Xu Yu Jin[b], Phillip Deverall[c]

[a]*Heart Centre, University Hospital of Northern Sweden, Umea, Sweden*
[b]*Oxford Heart Centre, John Radcliffe Hospital, Oxford OX3 9DU, UK*
[c]*BR1 2WZ, London, UK*

Received 14 March 2001; received in revised form 30 April 2001; accepted 18 May 2001

Between December 1997 and August 1998, 31 elderly patients (mean age 73) had aortic valve replacement using a Labcor stented porcine tricomposite bioprosthesis (Labcor Laboratories, Belo Horizonte Brazil). Doppler echocardiograms were performed at varying times in the postoperative period (4 days to 10 months). In the first week after implant four patients were found to have a high peak gradient across the left ventricular outflow tract (45, 55, 71 and 80 mmHg) with commensurate low effective orifice areas.

Following the mandatory reporting of this to the Swedish Health Ministry, the implant programme was stopped, and the subsequent media involvement ensured that there was wide publicity to the medical community and general public. A subsequent detailed analysis of the results illustrates the complexity of issues surrounding in vivo assessment of valve function and reveals some of the pitfalls that may occur when a new device or technique is introduced into clinical practice.

Our conclusions are:

1. Early non-invasive analysis may be misleading in patients with marked left ventricular (and outflow) hypertrophy and a normal or raised ejection fraction-in which circumstances a dynamic outflow obstruction can occur after relief of aortic stenosis [1,2]. This obstruction can take many weeks to resolve. This occurred in two of our patients.
2. Coexisting pathology must always be fully assessed. One patient proved to have severe paraprosthetic regurgitation that was not noted at discharged, but eventually found on invasive study. At redo valve replacement the porcine valve appeared normal.
3. One patient with a heavily calcified aortic root had a 23 mm valve inserted with difficulty. The valve was seated at an angle – a known cause of creating difficult echcardiographic assessment. The patient also had a body surface of >2.0 m [2], indicating possible biological mismatch.

In the clinical setting, it is important to investigate extreme values to determine why these patients deviate from the norm. Such individuals, if not recognized appropriately, can mislead and misinform. Further investigation may reveal that poor function is attributed to patient condition or limitations of the diagnostic methods, rather than device failure. Our analysis revealed that the unexpected rise in gradients as seen on echocardiographic examination was not device related. The Labcor stented porcine valve used in this series of patients was not defective and the performance of normal functioning Labcor valves was equivalent to that of other porcine bioprostheses [3–5].

The regulatory environment often dictates reporting and sharing of information. However, our experience emphasises the need for understanding data as it is reported. This experience illustrates the complex interrelationship between regulatory and legal demands, general clinical experience and the influence of a cautious clinical attitude, and the need to seek the truth in assessing a new technique or device by the fullest possible analysis.

References

[1] Dumesnil J, Yoganathan A. Valve prosthesis haemodynamics and the problem of high transprosthetic pressure gradients. Eur J Cardio-thorac Surg 1992;6(Suppl. 1):34–38.
[2] Jin XY, Pepper JR, Brecker JS, Carey JA, Gibson DG. Early changes in left ventricular function after aortic valve replacement for isolated aortic valve stenosis. Am J Cardiol 1994;74:1142–1146.
[3] Van Nooten G, Caes F, Francois K, Van Belleghem Y, Taeymans Y. Stentless or stented aortic valve implants in elderly patients? Eur J Cardio-thorac Surg 1999;15:31–36.
[4] Myken P, Bech-Hanssen O, Phipps B, Caidahl K. Fifteen years follow-up with the St. Jude Medical Biocor Porcine Bioprosthesis. J. Heart Valve Disease 2000(9):415–422.
[5] Wong SP, Legget ME, Greaves SC, Barratt-Boyes BG, Milsom FP, Raudkivi PJ. Early experience with the Mosaic Bioprosthesis: a new generation porcine valve. Ann Thor Surg 2000;69:1846–1850.

PII: S1010-7940(01)00869-7