

Safety of Comprehensive Aortic Root and Valve Repair Surgery: A Retrospective Outcomes Research by National Evidence-Based Health Care Collaborating Agency, Korea

Jong-Myon Bae, MD^{1,2}, Eunhee Shin, PhD¹, and Dae Seog Heo, MD^{1,3}

¹National Evidence-Based Healthcare Collaborating Agency (NECA), Seoul, ²Department of Preventive Medicine, Jeju National University School of Medicine, Jeju,

³Department of Internal Medicine, Seoul National University College of Medicine, Seoul, Korea

Comprehensive aortic root and valve repair (CARVAR) is a recently introduced surgical technique for aortic valve disease. The National Evidence-based Health Care Collaborating Agency was offered by the ministry of Health and Welfare, Korea to perform a retrospective outcome analysis for this surgical procedure. The aims of this study were to evaluate the safety of patients who underwent CARVAR surgery and to provide a rationale for further prospective randomized study. During the period of March 2007 to November 2009, 397 patients received this procedure and enrolled in this study. Clinical events including major bleeding, endocarditis, re-operation and death were followed-up till March 2010 by medical records. During the follow-up periods, 1-year cumulative incidence of major bleeding, re-operation, endocarditis and death were 3.55, 5.65, 5.05 and 5.33%/year respectively. This study showed that the CARVAR technique is not beneficial, and is indeed even more harmful than conventional valve replacement surgery. (**Korean Circ J 2012;42:769-771**)

KEY WORDS: Aortic valve; Heart valve diseases; Cardiac valve annuloplasty; Outcome assessment.

Introduction

The comprehensive aortic root and valve repair (CARVAR) procedure is, basically, one of the valve sparing surgical techniques for aortic valve or aortic root disease. Three basic surgical procedures of this technique are annular reduction, reduction of sinotubular junction (STJ) and leaflet correction.¹⁾² For reduction of the annulus or STJ, a commercially available sizing device, strip or ring and template (Sciencity Co, Seoul, Korea) are used.³ CARVAR procedure and devices, named and designed by Dr. MG Song, are under evaluation for list up process as new health technology by the Health Insurance Review

and Assessment Service (HIRA) from 2007. During this process, Han et al.⁴ reported 5 clustered cases of coronary ostial stenosis after CARVAR procedure. They also reported several cases of re-operation from valvular dysfunction or endocarditis and even cases of mortality after operation to the Korea Food and Drug Administration.

Under the debates on the safety and effectiveness of the CARVAR procedure, the Ministry of Health and Welfare, Korea offered a prospective randomized study. For the design and production of patient information for prospective study, it was required to establish a data of safety from previously performed operations.⁵

Subjects and Methods

Vitually the entire CARVAR procedure was performed by a single operator (Dr. Myeong Gun Song) at 2 university hospitals: from March 2007 to July 2007 at Asan Medical Center (Seoul, Korea) and from October 2007 to November 2009 at Konkuk University Hospital (Seoul, Korea). Three hundred ninety seven patients (26 cases at Asan Medical Center, 371 cases at Konkuk University Hospital) received CARVAR operation during this period and were enrolled for this study. Data from medical records were gathered by a trained investigator from National Evidence-based Health Care Collaborating Agency (NECA).

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Correspondence: Jong-Myon Bae, MD, Department of Preventive Medicine, Jeju National University School of Medicine, 102 Jejudaehak-ro, Jeju 690-756, Korea

Tel: 82-64-755-5567, Fax: 82-64-702-2687

E-mail: jmbae@jejunu.ac.kr

• The authors have no financial conflicts of interest.

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To obtain more complete information, a follow up was performed via 2 tracks including medical records of the out patient department and claim data of medical service in HIRA. Four major threatening clinical events including serious surgical bleeding requiring transfusion over 20 units of packed red blood cell, endocarditis, re-operation from any cause and death were focused for evaluation of safety. Clinical events at out patients' department were followed up till March 2010.

To compare with conventional valve replacement surgery, 337 patients without aortic root disease {aortic valve disease (AVD) only group} were analyzed separately. Total incidence during the follow up period (%) and 1-year cumulative incidence (%/year) were calculated by the Kaplan-Meier method. Clinical events that developed within 30 days after operation were defined as early events.

This study was approved by the Institutional Review Board of NECA (NECAIRB 10-001) and organized Data Review Board with 6 professional experts from the Korean Society of Thoracic and Cardiovascular Surgery and the Korean Society of Cardiology for peer data review.

Results

Baseline characteristics of patients are presented in Table 1. The mean age of overall patients was 53.3 ± 15.4 years. Importantly, there were 9 cases of age under 19 and 8 cases of older than 80 years-old.

Table 2 showed the outcome of CARVAR surgery. There were 20 fatal cases and 25 re-operated cases and 19 cases of endocarditis. Even in the AVD only group, the 1 year cumulative death rate was 4.41%/year and risk of re-operation was 5.81%/year.

Table 1. The baseline characteristics of overall patients and AVD only group

Variables	Overall (n=397)	AVD only (n=337)
Sex		
Male	218 (54.9)	187 (55.5)
Female	179 (45.1)	150 (44.5)
Age		
10-39	92 (23.2)	77 (22.8)
40-59	151 (38.0)	134 (39.8)
60-79	146 (36.8)	120 (35.6)
≥80	8 (2.0)	6 (1.8)
Previous medical history		
Hypertension	117 (29.5)	91 (27.0)
Diabetes mellitus	41 (10.3)	37 (11.0)
Angina pectoris	9 (2.3)	9 (2.7)
Stroke	28 (7.1)	25 (7.4)
Open heart surgery	50 (12.6)	45 (13.4)

Numbers in parenthesis means % of prevalence. AVD: aortic valve disease

Discussion

For the treatment of AVD, aortic valve replacement is regarded as a standard treatment. But, aortic valve sparing surgery can be applied to aortic regurgitation due to dilatation of the aortic root or ascending aorta without significant leaflet deformity. Theoretically, CARVAR is one of the aortic valve sparing surgical techniques. Hahm et al.¹⁾ described that the advantages of this technique are a wide range of indication, preservation of aortic root function, easy surgical technique and low recurrence of valvular dysfunction.

But, from the results of this study, the CARVAR technique failed to show any advantage in mortality and morbidity. In a recently reported 28 years experience (from 1982) of the Bentall procedure, the operative mortality was 5.5%, and risk of late reoperation and endocarditis were 3.2% and 1.4% respectively.⁶⁾ Moreover, Lim et al.⁶⁾ reported that, in patients with aortic root dilatation with advanced aortic regurgitation, operative mortality was 2.4% in the Bentall procedure group and 0% in the valve-sparing operation group.⁷⁾ Compared with those data, in patients with CARVAR surgery, mortality seems quite higher than recently reported results and the risk of endocarditis and re-operation are much higher than in previous reports. In the least, this procedure was not safer than conventional

Table 2. The overall incidence and 1 year cumulative incidence of 4 major clinical events in patients with CARVAR procedure

Clinical events	Overall	AVD only
Death		
Number of cases	20	13
Overall incidence (%)	5.04	3.86
1 year cumulative incidence (%/year)	5.33	4.41
Early incidence (%)	1.77	1.20
Re-operation		
Number of cases	25	21
Overall incidence (%)	6.30	6.23
1 year cumulative incidence (%/year)	5.65	5.82
Early incidence (%)	1.01	1.19
Endocarditis		
Number of cases	19	16
Overall incidence (%)	4.79	4.75
1 year cumulative incidence (%/year)	5.05	5.03
Early incidence (%)	1.27	1.50
Serious bleeding		
Number of cases	15	12
Overall incidence (%)	4.30	3.56
1 year cumulative incidence (%/year)	3.55	3.29
Early incidence (%)	3.28	2.97

CARVAR: comprehensive aortic root and valve repair, AVD: aortic valve disease

valve replacement strategy. This study has several limitations owing to fundamental problems. It was restricted in gathering enough clinical data from medical records, hence we could not evaluate data comprehensively. Nonetheless, the primary aim of this study is to provide basic safety data for further prospective randomized study. As such, it was fulfilled by the presented results.

Therefore, it can be suggested that the CARVAR procedure should undergo more in-depth investigation in consideration for the safety of patients.

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