What Are Necessary for Clinical Application of New Treatment Options?

Discussion for "CARVAR"

안전성 및 유효성 규명(2) - 임상의사 입장

울산대학교 의과대학, 서울아산병원 흉부외과 정 철 현



publications regarding "CARVAR"

"CARVAR" complication cases

AMC results(2007.4 - 2007.07)

Conclusion



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종합적 대동맥 근부 및 판막 재건술의 최근 초기 수술성적

이성준* · 신제균* · 김동찬* · 김진식* · 김준석* · 지현근* · 송명근*

Recent Early Operative Outcomes of Comprehensive Aortic Root & Valve Reconstruction (CARVAR) Procedure

Sung Jun Lee, M.D.*, Je Kyoun Shin, M.D.*, Dong Chan Kim, M.D.*, Jin Sik Kim, M.D.*, Jun Seok Kim, M.D.*, Hyun Keun Chee, M.D.*, Meong-Gun Song, M.D.*

Background: A Comprehensive Aortic Root and Valve Reconstruction (CARVAR) procedure is comprised of aortic root wall reconstruction and corrections of the leaflets for treating various aortic valve diseases. We evaluated our recent early clinical experience with the CARVAR procedure. Material and Method: From October 2007 to September 2008, 114 cases (66 males) of CARVAR procedures were performed. The mean patient age was 53 years (range: $14 \sim 84$). The patients were divided into 4 groups: 1) the AAR group: aortic regurgitation with aortic root wall deformity such as annulo-aortic ectasia or ascending aortic aneurysm (n=18), 2) the IAR group: isolated AR with leaflet abnormality (n=42), 3) the IAS group: isolated aortic stenosis (n=51) and 4) the PAVR group: previous aortic valve replacement (n=3). Sinotubular junction (STJ) reduction was done in all the patients, leaflet correction was done in 10 of the AAR group patients and in all the patients of the other groups, annulus reduction was done in 14 of the AAR group patients and in 6 of the IAR group patients. Aortic dissection was excluded from this analysis. Result: There was no mortality or follow-up death. The diameter of the aortic sinus decreased from 54.6±8.4 mm to 38.3±3.8 mm in the AAR group, the mean AR grade decreased from 3.2 to 0.2 in the IAR group, the mean aortic valve pressure gradient decreased from 47.1±24.4 mmHg to 15.1±11.7 mmHg in the IAS group and the mean AR grade decreased to 0 in the PAVR group. Balloon type coronary perfusion cannula-related coronary ostial stenosis developed in 4 patients and this was treated with OPCAB in three patients and with PTCA in one patient. Two patients developed postoperative infectious endocarditis. All the patients were discharged and followed up in a stable condition. Conclusion: The CARVAR procedure showed excellent short term results, but a good further follow up result is required to apply this procedure to most kinds of aortic valve diseases.

(Korean J Thorac Cardiovasc Surg 2009;42:696-703)

Notice about article: Lee SJ, Shin JK, Kim DC, Kim JS, Kim JS, Chee HK, Song MG. Recent early operative outcomes of comprehensive aortic root & valve reconstruction (CARVAR) procedure. Korean J Thorac Cardiovasc Surg 2009;42:696-703

Editorial committee of the Korean Journal of Thoracic and Cardiovascular Surgery

This article was reviewed by the editorial committee of the Korean Journal of Thoracic and Cardiovascular Surgery.

Any author who is going to cite this article for writing, must consider the facts listed below which were found during review of this article.

Study group enrolment

- 3 cases of "converting to AVR during CARVAR operation" were omitted.

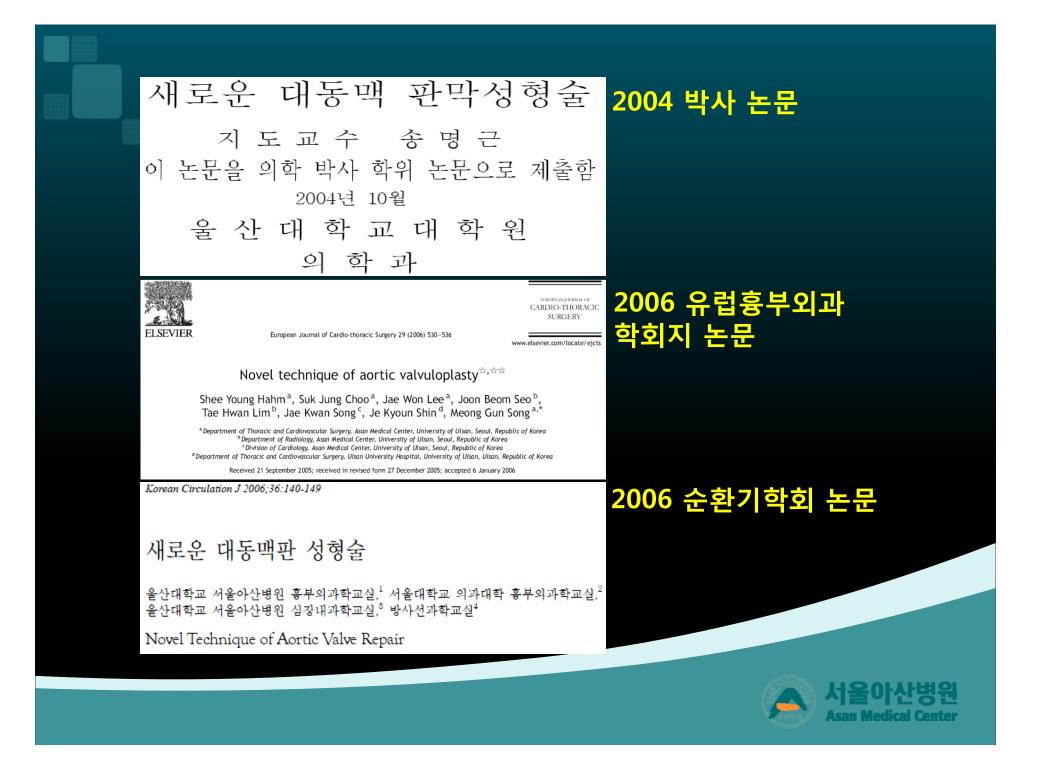
- Re-do CARVAR case was not included.

Complication

- Important complications such as postoperative endocarditis, bleeding, arrhythmia, heart failure were not completely evaluated in this study.

Follow up

- Postoperative AR grading scale criteria was not clear. This may affect the conclusion of this article in terms of "favorable outcome of CARVAR operation".



	2004 박사 논문	2006 유럽논문	2006 순환기학회
대상기간	1997.12~2004.10	1997.12~2004.12	1997.12~2005.4
대상 환자 수	65+49	69	75
대상 질환			
AD	49	0	0
IAR	35	30	35
AAR	13	22	22
AAE	17	17	18
IRB 통과 유무 기재	-	+ (허위기재)	-
식약청 승인 기재	-	+ (허위기재)	+ (허위기재)
			서울아산병 Asan Medical Cen

수술 후 판막기능

수술 직후 심초음파 결과

104명(91%)에서 수술 후 대통맥판막 폐쇄부전의 등급(grade)이 2도를 넘지 않았다. 3도를 넘은 환자들은 5명이었는데 평균 8개월의 추적관찰기간 동안 시행한 심초음파 검사에서는 36명의 환자 중 32명(89%)에서 대통맥판막 폐쇄부전이

없어졌다.

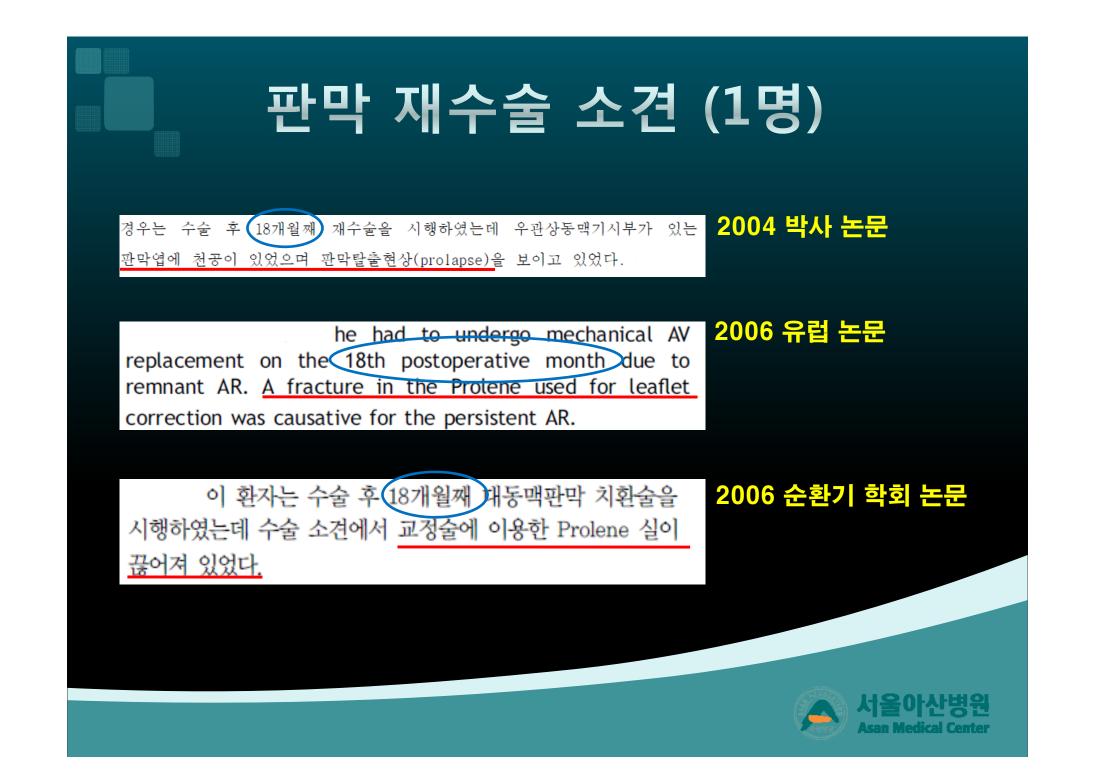
No patient, except for the reoperated patient had AR greater than grade 2.

수술 직후 심초음파 결과 ; 수술 직후 75명 중 69명(92%)의 환자에서 대동맥판 폐쇄 부전증 의 등급이 2도를 넘지 않았다. 3도 환자는 6명이었는데, 이 중 3명 은 수술 전 4도에서 호전되었으며 나머지 3명은 수술 전과 변화가 없었다

2006 유럽 논문 2006 순<u>환기 학회 논문</u>

2004 박사 논문





	2004 박사 논문	2006 유럽논문	2006 순환기학회	
수술 직후 AR ≥ 3+	5	3	6	
지속적 AR ≥ 3+	4 (2)*	1	2	
대동맥 판막 재수술	2 (1)*	1	1	
대동맥 판막 재수술	Leaflet perforation	Prolene suture	Prolene suture	
소견	and prolapse	fracture	fracture	
*(patents with aortic dissection)				
			서울아산병원 Asan Medical Center	



◈ 각각 발표된 논문 상 불일치 하는 data가 많음

◈ 더욱 중요한 것은 성적이 우수하게 나타나도록 data가 조작 되었다는 점임

◈ 판막성형술은 수술직후나 단기 결과보다는 장기 성적이 더욱 중요한데, 초기 성적만 발표되고 장기 성적은 알려지지 않고 있다







김용인 교수 "단순 링 넣는 수준 아닌 획기적인 기술… 의료계 소통 필요 日 의료계선 토론 분위기 진지… 무조건 반대 국가적 손실"



최종범 교수

"기존 판막 기능 그대로 살리느냐 통째로 바꾸느냐의 차이 보의연 보고서 엉터리 많고 조잡-- 감사원 감사 받아야"

복지부 앞에서 항의시위 카바수술 환자들

2011,11,02 21:38 입



찿아가 항의했을 것이다. 우리가 복지부 앞에 왜 모였는지 관계당국 공무원들과 의료진든 깊이 생각해봐야 할 것이다."

카바수술 신의료기술 평가를 둘러싸고 정부와 학계, 시술자간 갈등이 끊임없이 이어지고 있는 가운데 이 수술을 받은 환자들이 논란의 조속한 해결을 요구하며 적극적인 목소리를 내고 나섰다.

1cm distal to the aortic commissures. The aortic wall was resected and the coronaries were trimmed as buttons to be

CARVAR가 아닌Yacoub 수술을 시행. CAVAR ring도 들어가 있지 않고 Leaflet 에는 아무 procedure도 안함

수술기록지

Assistants 주석중 / 제형곤 / 윤석원

Sex/Age 님 / 36 Yr

87.3 kg 205.0 cm 2.22 m²

Procedure

In supine position, the patient was prepped and draped in the usual manner. Anesthesia was conducted under continuous

Staff : 송명근 M.D.

M.D.

W'D'

EKG and arterial pressure wave monitoring. The chest was

Chart No. 14714120 ID No. 640607-1479015 Name 환기법

AAE with Martan

Bwt / Ht / BSA

OpType Elective

Root remodelling or replacement

Date of Op 2000-03-16

송명근

A3410

A341

Findings

leaflets.

Normal cardiomedaly, No AR

Marfan's SD Ascending aortic aneurysm

Aortic root remodelling

Extremely dilated and thinned sinuses of valsalva of all three

Op Name : Aortic root remeiling with cotonary transfer and AVP

Described by

Descuped px

Anesthesia GEA

Operator

진단(기술)

수술코드

수술(기술)

진단코드

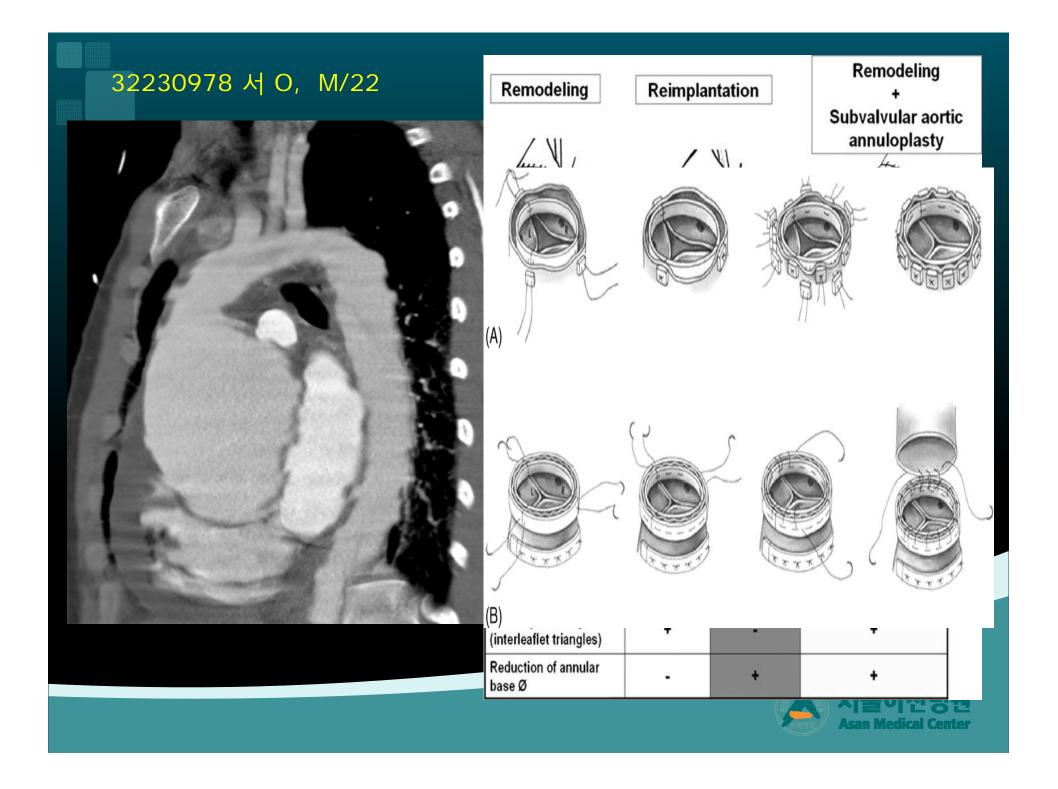
according to the technique as described by Yacoub and associates. The isolated coronaries were then reattached as buttons with #6-0 continuous prolene sutures to the respective coronary sinuses. The distal end of the graft was then anastomosed to the distal ascending aorta. After release



대동맥근부 확장증이 있는 Marfan환자에게 시행된 유사" CARVAR"수술의 합병증 사례보고 ---

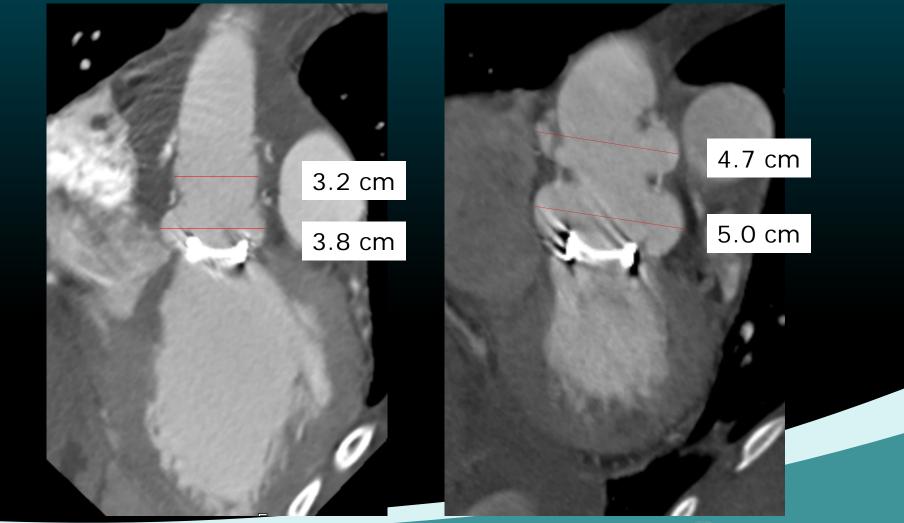
확장부위를 절제하지 않고 " CARVAR" 링으로 고정한 후의 변화





32230978 서 0

2005.8.22; (AMC technique; avoiding Bentall op , AVR with Mira 25mm, inner ring 28mm, outer ring 38mm)



2005-08-29 Immediate postop. CT

2010-6-5 CT

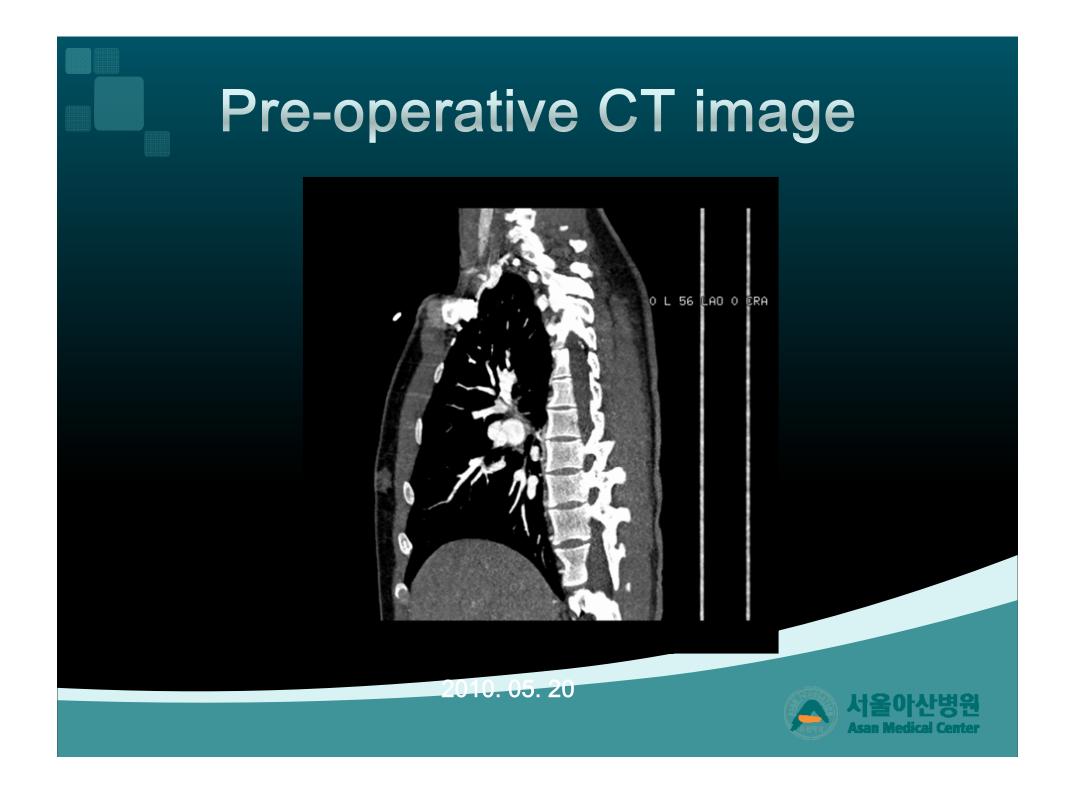


22 year old male Marfan patient

2005. 8.22, 1st op

F/U dissection CT; sinus dilation increased gradually 수술 필요성 경고 but neglected 2010.5.8; acute type B aortic dissection developed





- 건국대 ER visit but op refused

- 2010. 5.31 ; TAAA replacement at AMC
- sinus dilation increased more and more
- 2011. 4.14; redo- Bentall op

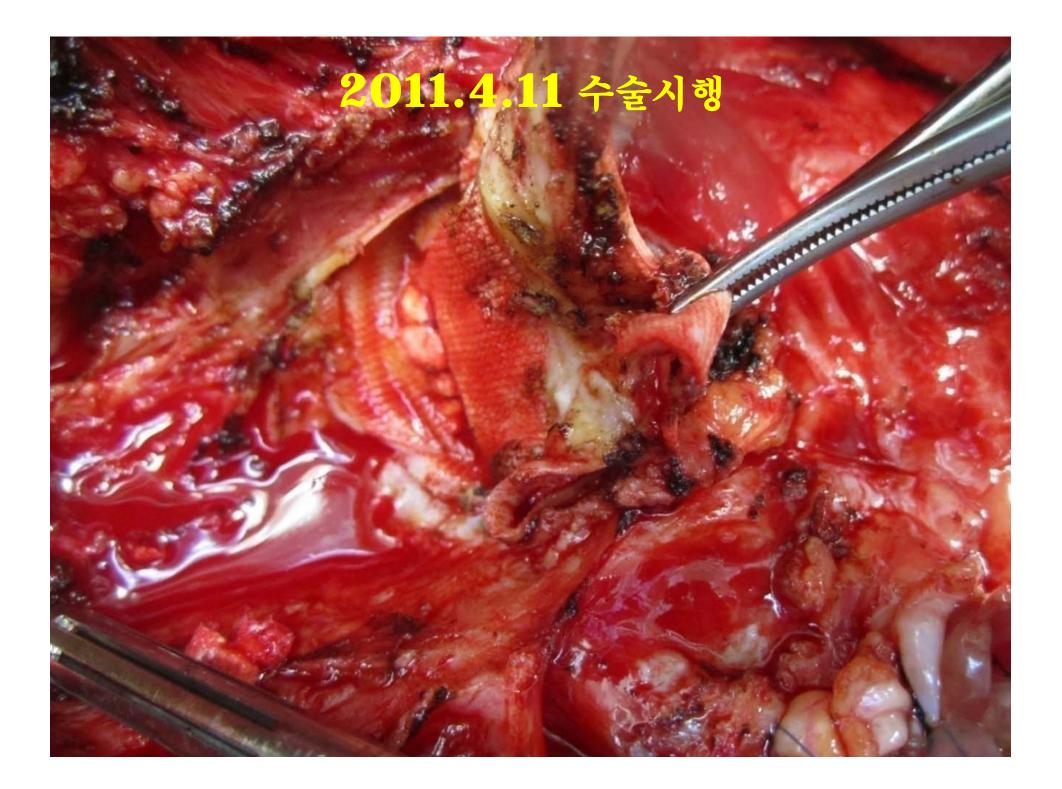


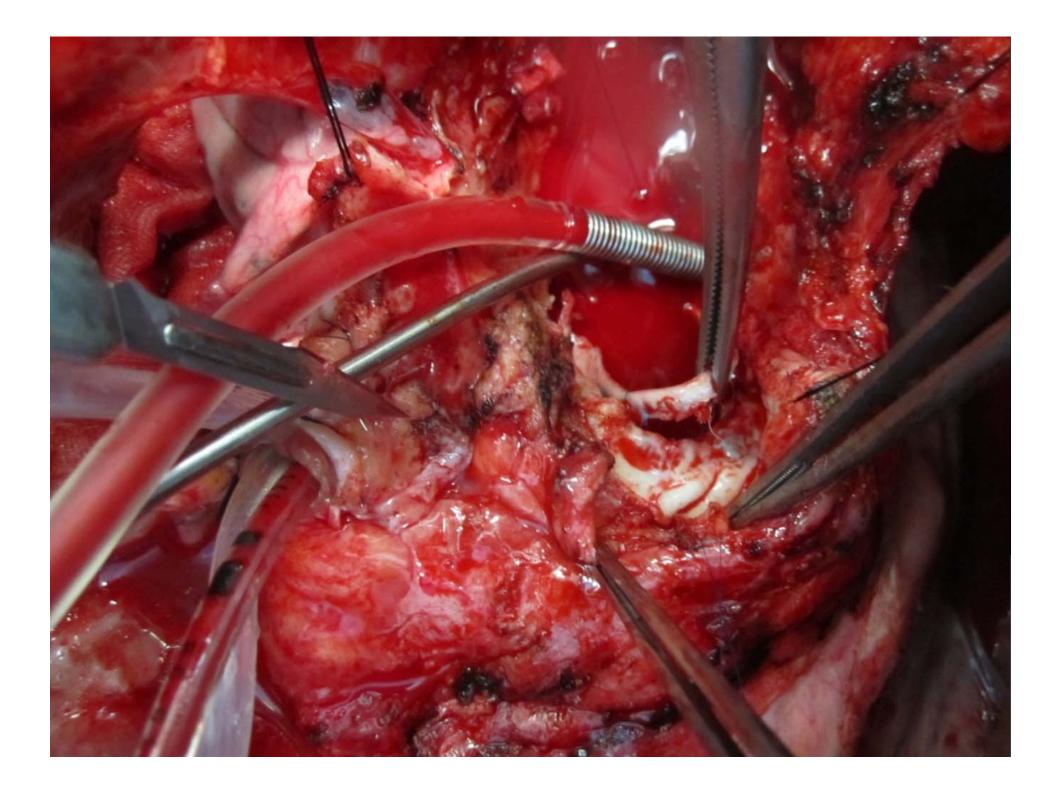
Post-operative CT image

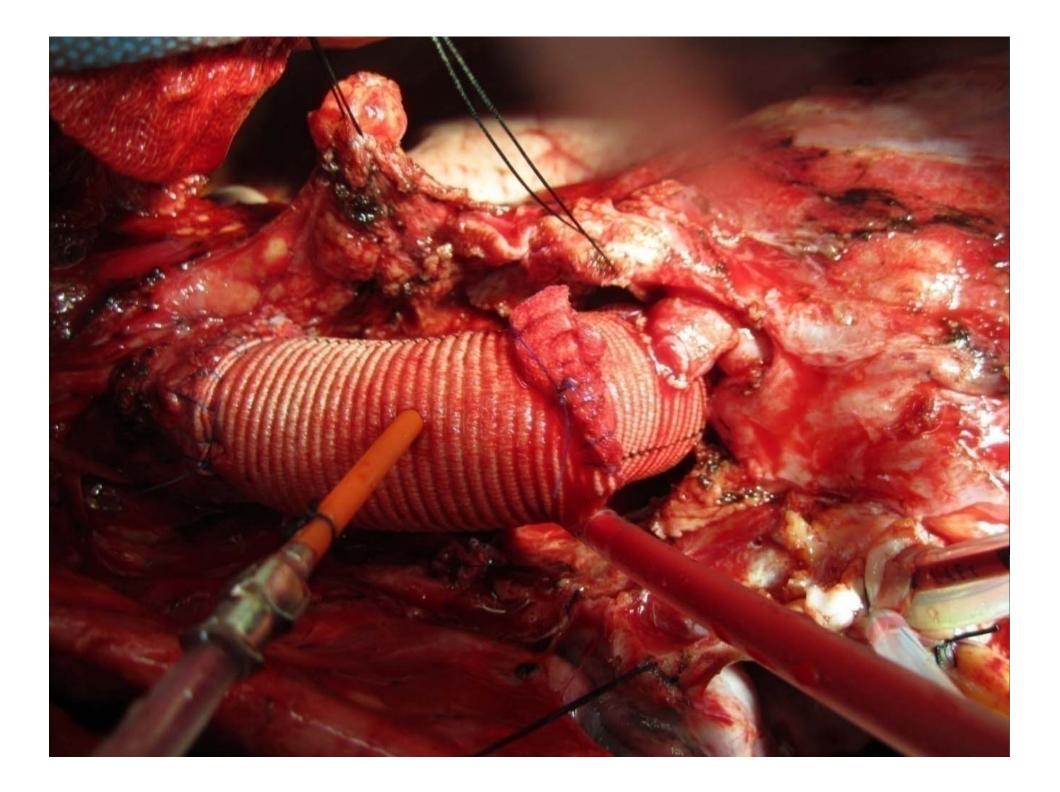




2010.06.05











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CASE REPORT

Isolated aortic root dilatation following sinotubular junction reduction using prosthetic rings

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Abstract

'Comprehensive Aortic Root and Valve Reconstruction' technique, which was first introduced in 2005 involves aortic root reduction using prosthetic rings in order to preserve the native aortic sinuses in patients having aortic regurgitation associated with aortic root dilatation. We report a case of isolated aortic sinus aneurysm in a Marfan syndrome patient following the aortic root preserving surgery in the presence of ascending aorta aneurysm and annuloaortic ectasia. Re-operation consisted of aortic sinus resection and replacement with an artificial graft, and coronary reimplantation using a button technique. Close follow-up is essential for patients who underwent aortic root preserving surgery to appropriately manage this kind of complication.

Keywords: Aortic root · Aortic valve repair · Aortic aneurysm · Re-operation

CASE REPORT

A 27-year old, Marfan syndrome male patient presented with marked aortic sinus dilatation. Six years before he underwent replacement of the ascending aorta and hemiarch (Vascutek graft, 24 mm, Renfrewshire, Scotland, UK), sinotubular junction reduction using prosthetic rings (ScienCity Co., Seoul, Korea) and mechanical aortic valve replacement (Edwards MIRA, 25 mm, Edwards Lifesciences, Irvine, CA, USA) for the treatment of annuloaortic ectasia, ascending aorta aneurysm and severe aortic insufficiency (Fig. 1). During the prior operation, reduction in enlarged aortic root was attempted by inserting two prosthetic rings, inner ring (28 mm) and outer ring (38 mm) (ScienCity Co., Seoul, Korea), which were attached to the inner and outer surface of the aortic root, proximal to the coronary ostium. Another 26-mm sized ring was attached to the intima of the sinotubular junction, distal to the coronary ostium. Five years after initial surgery, he underwent thoracoabdominal aorta replacement (from proximal descending aorta to the supra-celiac level) for the treatment of dissecting aneurysm of thoracoabdominal aorta without postoperative complications.

At the current evaluation, the follow-up computed tomography (CT) images revealed an aortic sinus aneury-smal dilatation up to 60 mm in diameter at the level of the aortic sinus between the mechanical aortic valve (Fig. 2) and the prosthetic rings, and hence an elective operation was planned. Intraoperatively, the proximal part of the aortic sinus was severely dilated, leaving only the prosthetic rings attachment site relatively intact in its mechanical valve with horizontal mattress sutures. Coronary artery was reimplanted with the coronary button technique. Cardiopulmonary weaning was successfully done. The patient's condition was complicated with acute renal failure, which was managed with temporary (21 days) haemodialysis. The follow-up CT findings were unremarkable, showing patent sinus graft and reimplanted coronary arteries without flow disturbances. The urine output progressively increased to finally recover normal renal function. The patient was discharged on 38th postoperative day, without complications.

DISCUSSION

Comprehensive Aortic Root and Valve Reconstruction technique (CARVAR) was first introduced by Song *et al.* in 2005 [1]. This technique involves the reduction of the aortic root size using prosthetic rings that are attached to the inner and outer surface of the sinotubular junction, and thereby correction of associated aortic insufficiency is expected in patients with aortic insufficiency secondary to aortic root enlargement. In selected cases, leaflet extension was combined using bovine pericardial patch according to the presence of leaflet deformity or incomplete coaptation. Reports of consecutive series of the CARVAR technique were followed, with excellent short- and mid-term results [2, 3].

Unlike David- or Yacoup-type aortic valve sparing procedure, in this technique, aortic sinus tissue remained intact in the expectation of sinus function preservation. In their reports, the ra-

Shee Young Hahm^a, Suk Jung Choo^a, Jae Won Lee^a, Joon Beom Seo^b, Tae Hwan Lim^b, Jae Kwan Song^c, Je Kyoun Shin^d, Meong Gun Song^{a,*}

European Journal of Cardio-thoracic Surgery 29 (2006) 530-536

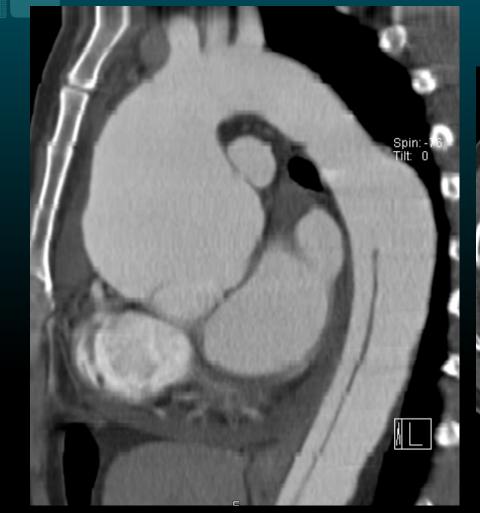
Table 1 Preoperative patient profiles

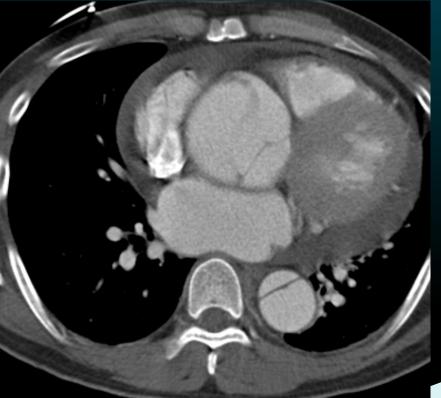
Variables	IAR	AAR
Number of patients	30	39
Age (mean \pm SD (range))	43.4 ± 14.0 (17–68)	49.5 ± 17.3 (16-73)
Sex (M:F)	19:11	26:13
Causes of AR		
Ascending aortic aneurysm		22
Annuloaortic ectasia		17 (13)
(Marfan's synd)		
Isolated AR	30	
Main leaflet pathology	30	17
Leaflet thickening	16	5
Leaflet prolapse	6	5
Degenerative change	1	2
Bicuspid aortic valve	1	2
Quadricuspid aortic valve	1	
Commissural detachment	2	1
Infective endocarditis	2	
Aortic steno-insufficiency	1	2



SD, standard deviation; AR, aortic regurgitation; synd, syndrome.

32130100 44/M 이O우

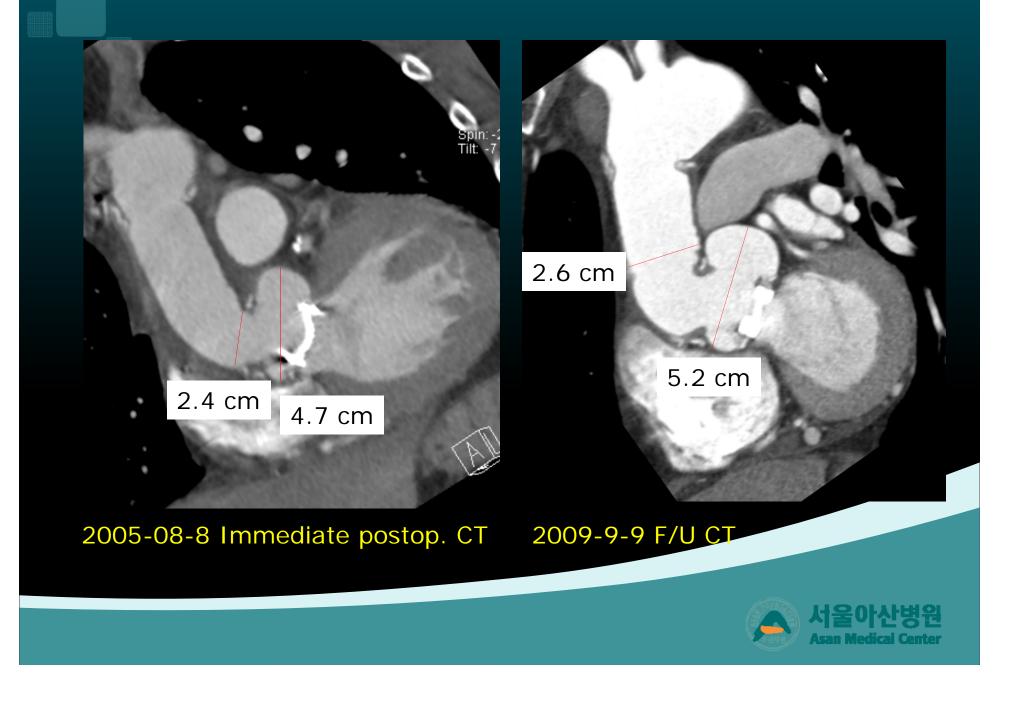




2005-7-27 Preoperative CT



32130100 44/M 이O우





Preoperative Diagnosis

; Severe AR, focal narrowing of abdominal aorta, Takayasu arteritis, HTN

Operation : 2007.01.03

- AVP (AMC technique, new leaflet formation, inner 26mm, outer 34mm)
- Axillo-femoral bypass (10mm Gore-Tex graft)



Postoperative follow-up (op; 2007,1,3)

- 2007. 01.08 postop f/u echo : Trivial AR after AVP
- 2007. 07.18 postop f/u echo : Trivial AR, r/o edematous change of NCC
- 2007. 08 ~ 2010.12 : 건국대학교 병원 CS, CV follow-up
- 2010. 11. 29 건국대 병원 Echo F/U due to moderate to severe dyspnea developed

Echo; but no information or suggestion at all to the patient

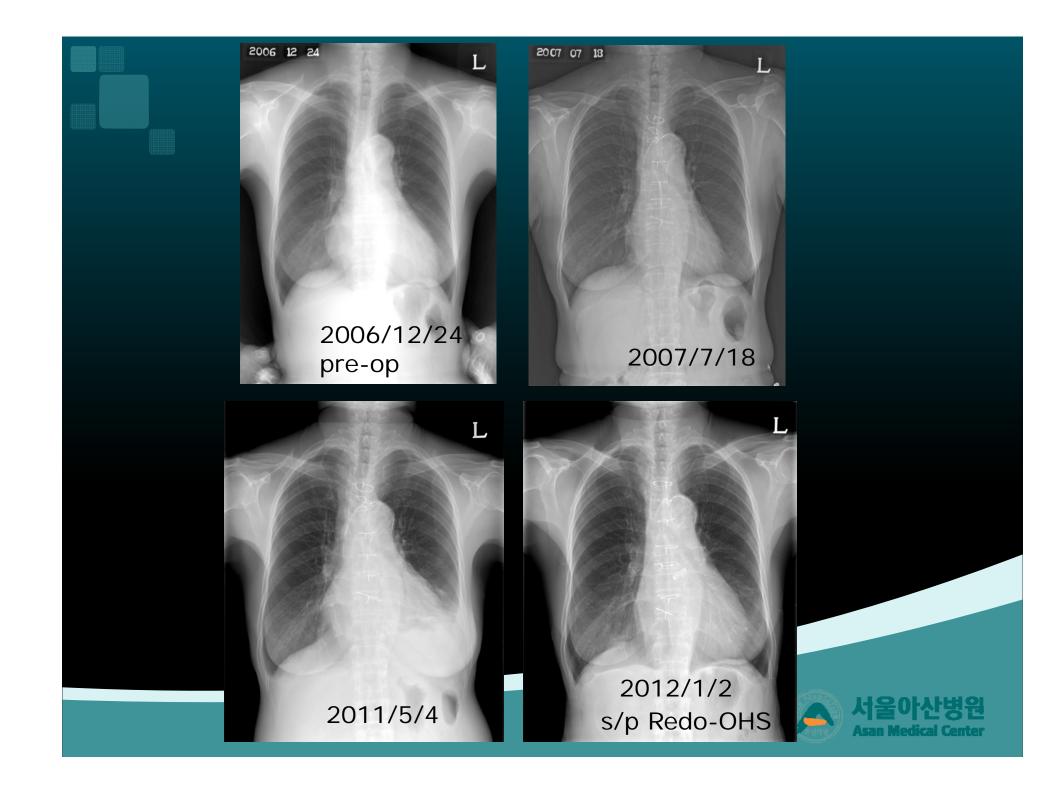
- 2011. 05 .17 : generalized edema 동반한 dyspnea 점점 악화되는 소견 보여

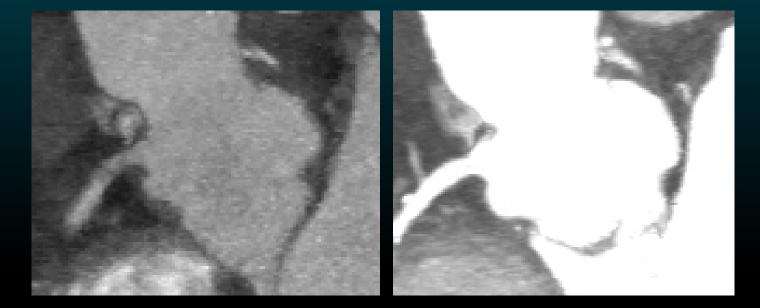
본원에서 Echo 시행; severe AR with detachment of neoleaflet

Redo operation : 2011.05.27

- Redo AVR (Top-hat 19mm),
- Asc. Ao. Replacement (Hemashield 28mm)



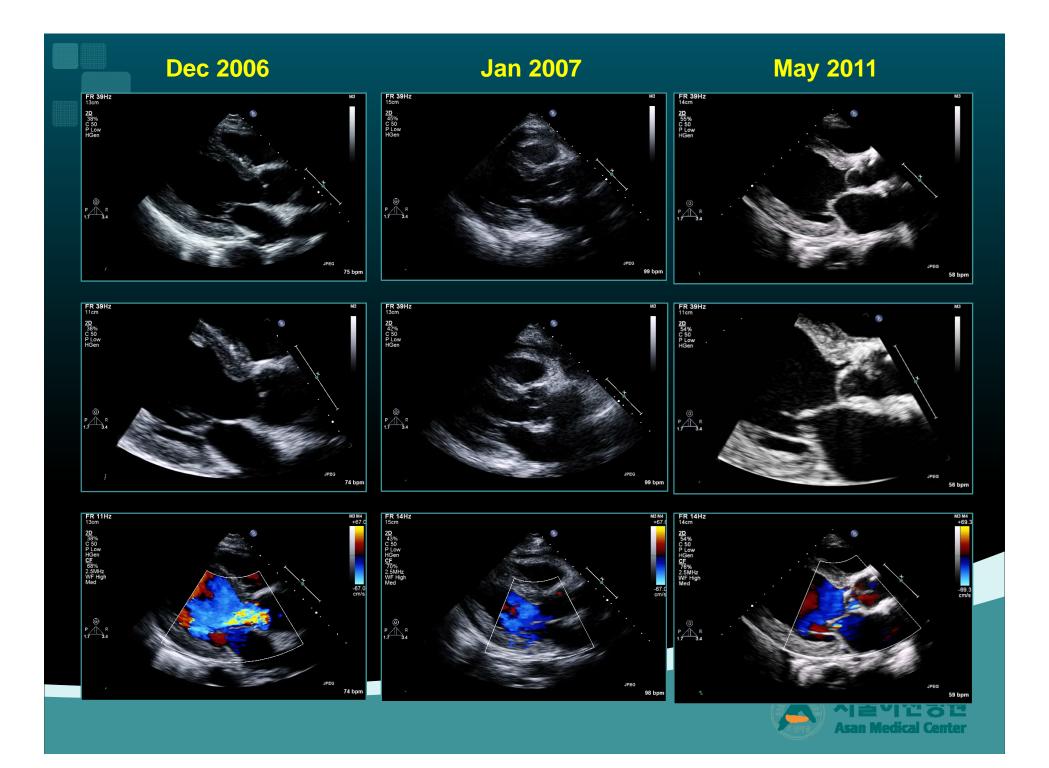




2007/1/9 Immediate post-CARVAR

2011/5/26 Before Redo-OHS





Nov.2010 건국대

May 2011 AMC

Jan 2012 reop













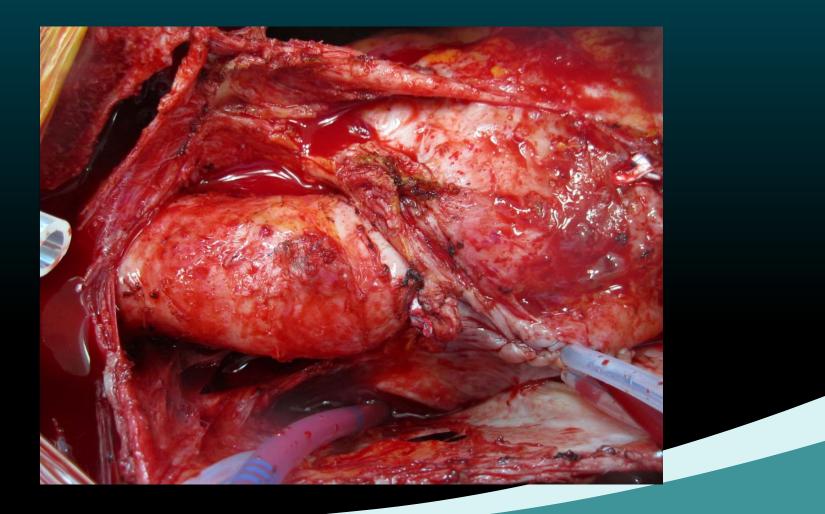




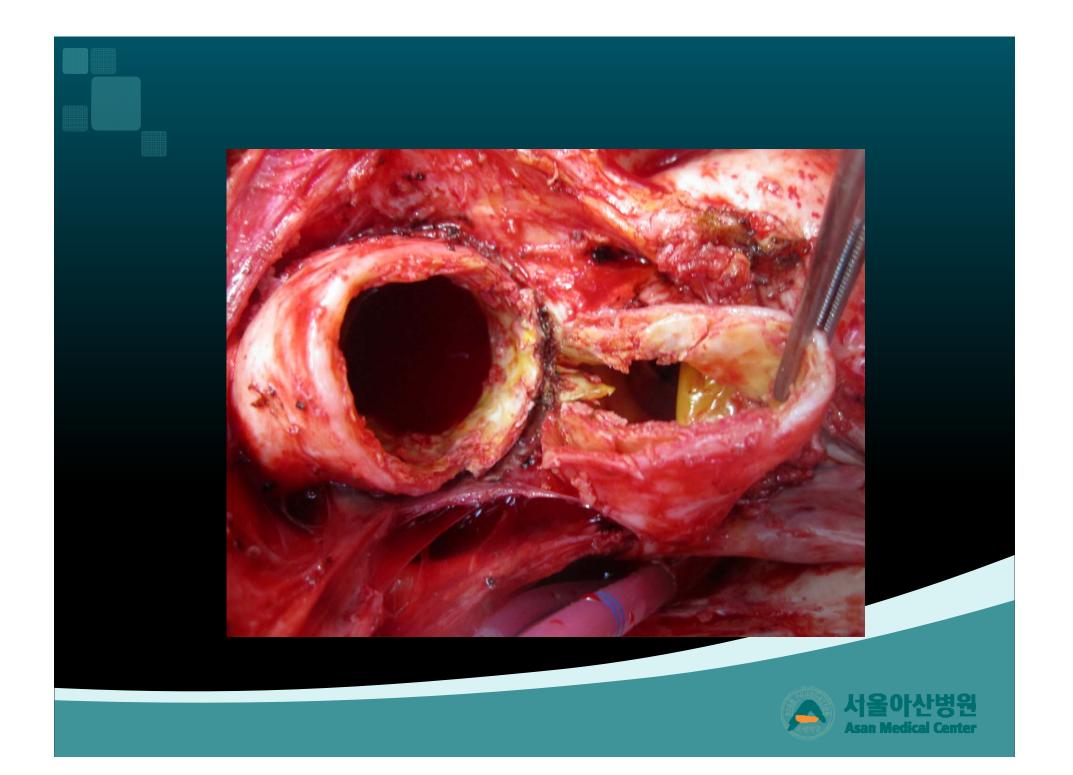


Asan Medical Center

Op finding at redo-operation

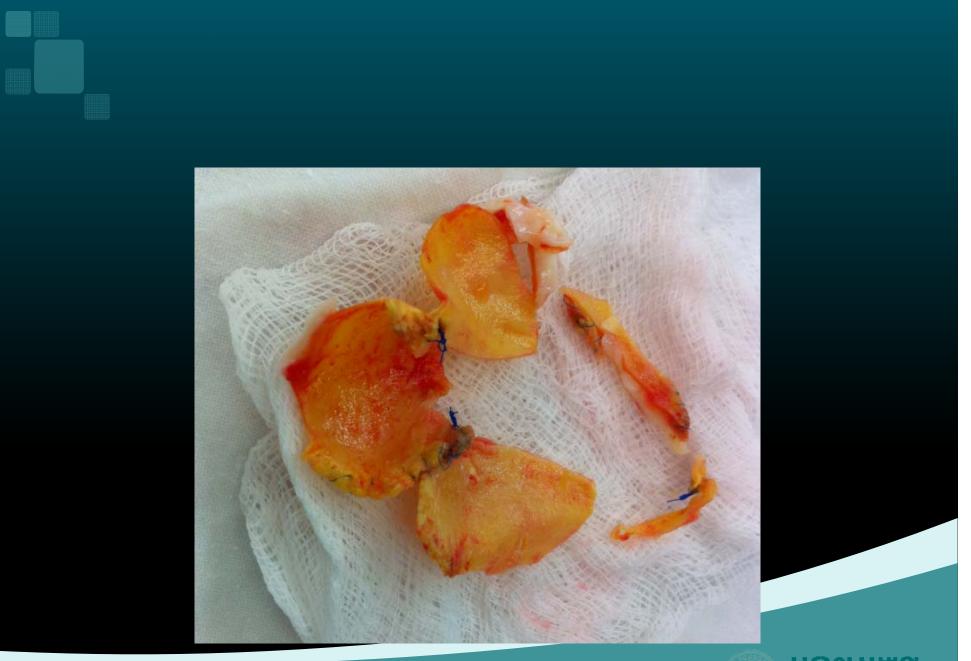














문제점

◈ 빙산의 일각;

- 대동맥 근부가 확장된 환자는 일반적으로 증세를 호소하지

않기 때문에 수술 후 환자들의 추적 관찰 시 주기적인 초음파나

CT 검사를 적절히 하여 정확한 정보를 주지 않으면 환자 본인은 알 수가 없어

적절한 수술시기를 놓치거나 급사할 수 있다.

- 상기 사례에서와 같이 계속 환자가 발생되고 있으나 대부분의 수술 후
 환자관리는 건국대 측에서만 시행되고 있기 때문에 문제가 있을 수 가능성이
 있는 환자가 상당수 은폐되고 있는 것으로 추정된다.



CARVAR in Asan Medical Center

from April.07 to July.20 2007

N = 30



CARVAR in Asan Medical Center

Profiles	Number of patients (%)
Female gender	8 (26.7)
Aortic valve pathology	
AAE with AR	10 (33.3)
Isolated AR	7 (23.3)
Isolated AS	8 (26.7)
ASR	3 (10.0)
SBE	1 (3.3)
Chronic aortic dissection without AR	1 (3.3, Marfan syndrome)
Combined operation	
Ascending aorta replacement	12 (40)
CABG	2 (6.6)
MV repair	5 (16.7)
TV repair	2 (6.6) 서울아삼병원
AF ablation	2 (6.6)

CARVAR in Asan Medical Center

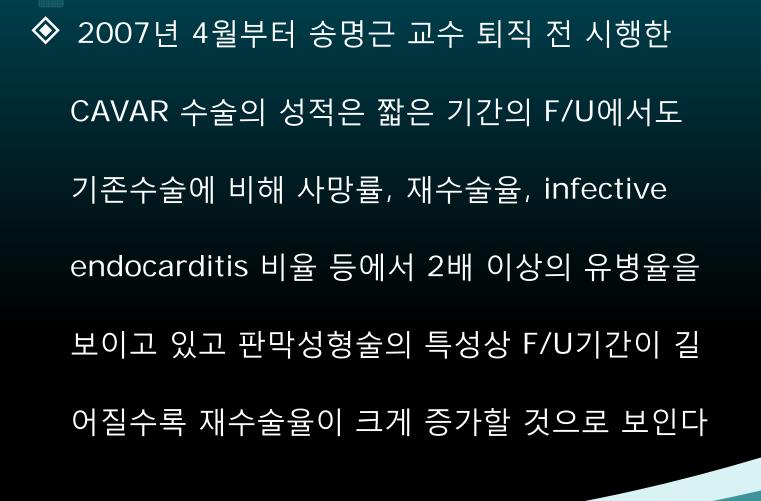
Major complications

- ; 3 in-hospital deaths (10.0%): IE in 2, intractable bleeding in 1
- ; Infective endocarditis in 2: all underwent reoperation and died
- ; Aortic valve reoperation in 4: Bentall operation in 3 (1 patient underwent 4 operations) and AVR in 1
- ; Aortic valve dysfunction (AR≥3 or AV mean PG> 30mmHg); n=13 (AR in 8, AS in 5). Of them 4 underwent reoperation



Patient			OP. Name		
ID	Name	OP.Date	DX	OP. Name	
34850000	정미x	2007.04.21	SBE. Root abscess	CARVAR	
			AR. MR. TR.	with asc. A. replacement , MVP. TAP	
		2007.08.03	IE. AR	Redo Bentall(prima plus 21mm	
34940000	정기x	2007.06.13	AR.	CARVAR	
		2007.06.20	Severe AR.	VSD patch closure	
			latrogenic VSD		
		2007.07.03	Complete AVBlock	pacemaker Insection	
		2007.07.13	failure of prev. AR repair	Redo Bentall with prima plus	
				MAP	
				Ascending a replacement	
35180000	황봉x	2007.07.20	AR.	CARVAR	
		2007.08.01	failure of prev. AR repair	MVR with Mira valve	
				Bentall op with S-J AUG 25mm	
		2007.10.11	pseudoaneurysm of	Redo Bentall with Homograft	
			LVOT(rapture to RA)	Ascending a replacement	
34760000	이옥x	2007.04.02	Asr	CARVAR	
		2007.07.25	failure of prev. repair	AVR Mira 19mm	
				Ascending a replacement	LAH

Asan Medical Center





Long-term results of aortic valve-sparing operations for aortic root aneurysm

Tirone E. David, MD, Christopher M. Feindel, MD, Gary D. Webb, MD, Jack M. Colman, MD, Susan Armstrong, MSc, and Manjula Maganti, MSc

J Thorac Cardiovasc Surg 2006;132:347-54

- 1988-2005:
- 220 consecutive patients who had aortic valve sparing for aortic root aneurysm



Long-term results of aortic valve-sparing operations for with aortic root aneurysm

David et al. J Thorac Cardiovasc Surg 2006

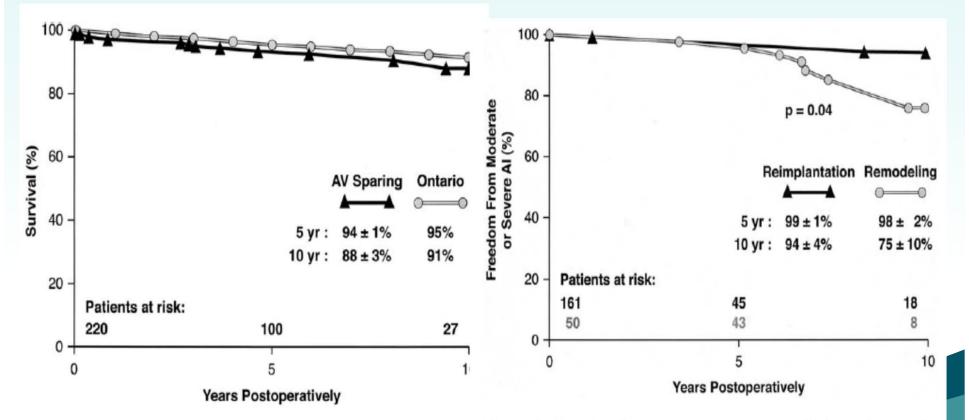


Figure 1. Survival of patients after aortic valve-sparing opera tions compared with survival of age- and sex-matched genera population of Ontario.

Figure 3. Freedom from moderate or severe AI in patients who had reimplantation of the aortic valve and remodeling of the aortic root.

Aortic Valve Repair Using a Differentiated Surgical Strategy

Frank Langer, MD; Diana Aicher, MD; Anke Kissinger, Olaf Wendler, MD; Henning Lausberg, MD; Roland Fries, MD; Hans-Joachim Schäfers, MD

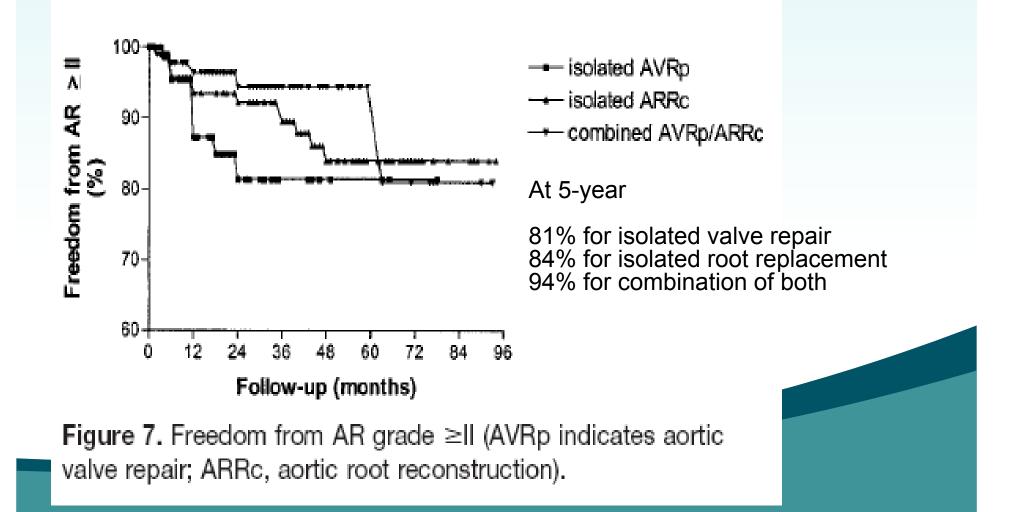
Circulation. 2004;110[suppl II]:II-67-II-73..

1995 to 2003 AV repair in 282 of 493 patients (57.2%) undergoing surgery for AR



Aortic Valve Repair Using a Differentiated Surgical Strategy

Langer et al. Circulation 2004



J Thorac Cardiovasc Surg 2009;138:859-64

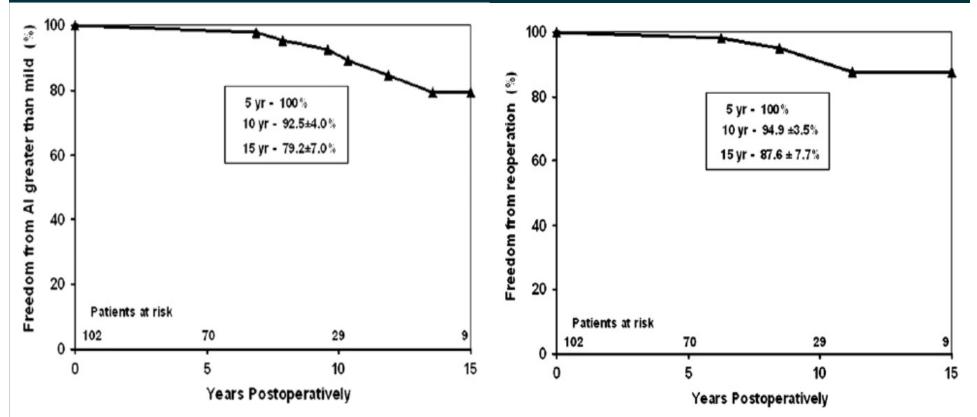


FIGURE 3. Kaplan–Meier estimates on freedom from aortic insufficiency (*AI*) greater than mild after aortic valve–sparing operations.

FIGURE 2. Kaplan-Meier estimates on freedom from reoperation on the aortic root after aortic valve-sparing operations.



Midterm Results of Aortic Valve Replacement Using Tissue Valve

Dukhwan Moon, M.D.*, Jae-Won Lee, M.D.*, Yun Seok Kim, M.D.**, Won-Chul Cho, M.D.*, Sung-Ho Jung, M.D.*, Suk-Jung Choo, M.D.*, Cheol-Hyun Chung, M.D.*

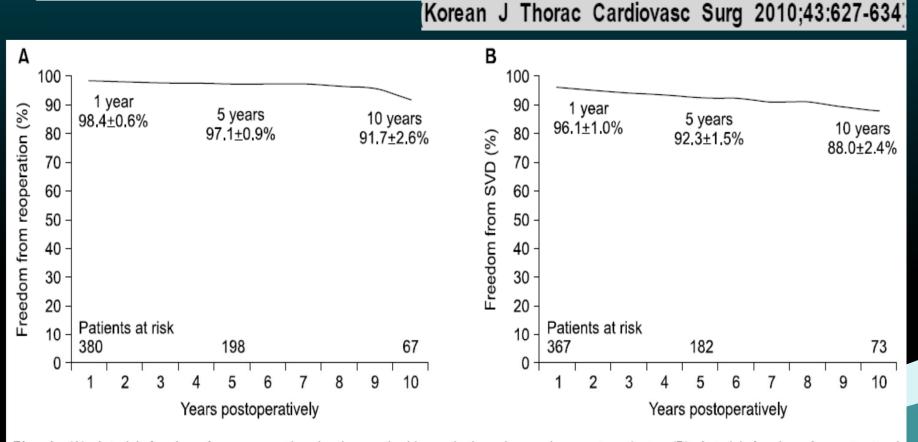


Fig. 4. (A) Acturial freedom from reoperation in the aortic bioprosthetic valve replacement patients. (B) Acturial freedom from structural valve deterioration (SVD) in the aortic bioprosthetic valve replacement patients.



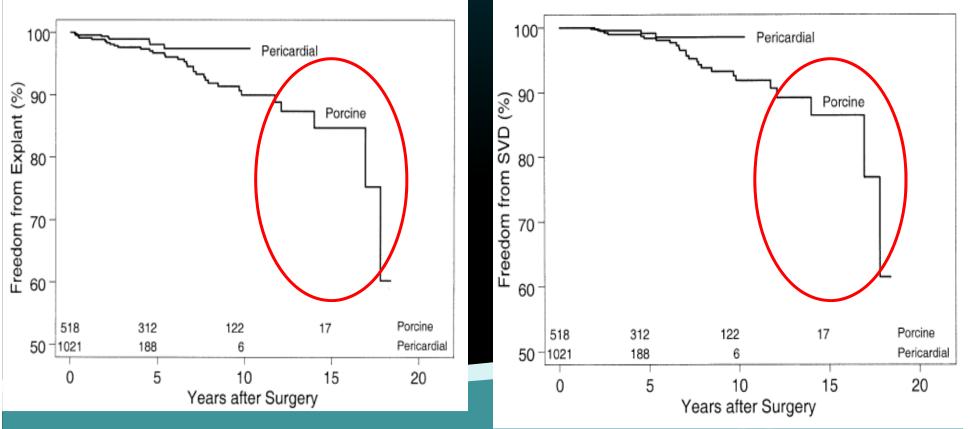
Journal of the American College of Cardiology © 2004 by the American College of Cardiology Foundation Published by Elsevier Inc. Vol. 44, No. 2, 2004 ISSN 0735-1097/04/\$30.00 doi:10.1016/j.jacc.2004.01.053

Durability of Pericardial Versus Porcine Aortic Valves

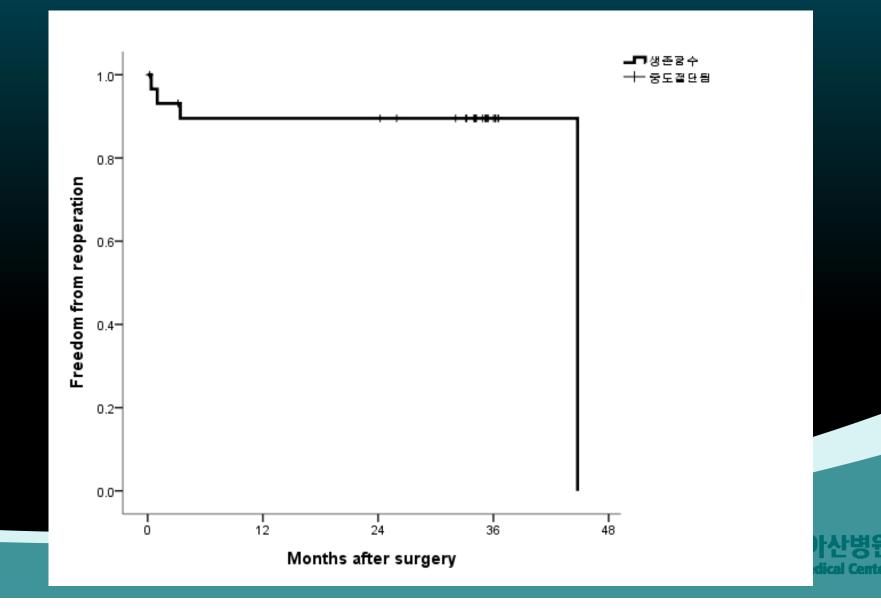
Guangqiang Gao, MD, YingXing Wu, MD, Gary L. Grunkemeier, PHD, Anthony P. Furnary, MD, Albert Starr, MD

Portland, Oregon





Freedom from reop. at 2 years : 89.5 ± 5.7% CARVAR in Asan Medical Center



Conclusions

CARVAR 수술...

혁명적 '의술'인가 위험한 '사술'인가



Decision Letter

From: ats@uphs.upenn.edu Subject: The Annals of Thoracic Surgery MS ID# ATS/2004/070433 Cc:

The Annals of Thoracic Surgery MS ID#: ATS/2004/070433

MS TITLE: Novel technique of aortic valvuolplasty



Reviewer 1 Comments for Author

 … Doctor Song and colleagues describes that "A new durable technique for aortic valve repair was developed" <u>but not</u> <u>a single component of their "novel technique" is really</u> <u>novel.</u>

Actually, if they had reviewed the literature more carefully they would have found that <u>every part of their complex</u> <u>aortic valve repair has been described before.</u>

Reduction of the diameter of the aortic annulus was described by **Tirone David** during the 1990's. Aortic cusp augmentation or creation with glutaraldehyde fixed autologous pericardium was first described by the late **Ake Senning** and extensively used by **Carlos Duran** during his experience in Saudi Arabia. Aortic cusp reduction was described by **George Trusler** in patients with sub-aortic VSD and by **Alain Carpentier**, **Delos Cosgrove**, **Tirone David**, **and Hans Schaeffer** for myxomatous bicuspid and tricuspid aortic valve disease with prolapse. Reduction of the diameter of the sinotubular junction to increase aortic cusps coaptation was first described by **Frater** and extensive published by **David**. "Sandwiching" the aortic root with two strips of synthetic fabric is as old as operations for aortic dissections and extensively published by **Craig Miller**. What the authors have done is combining a number of these techniques in a variety of pethologie process involving the aortic root.



Reviewer 1 Comments for Author

The paper is not well written. The introduction has several erroneous interpretations of the work by other authors. The description of the operative procedure is unclear. The authors failed to determine the mechanism of AI in each sub-group of patients who had their "novel" technique, and did not quantitate the reductions, additions, etc. on the various components of the aortic valve.



Reviewer 2 Comments for Author

In the second second



Reviewer 3 Comments for Author

Currently the series includes multiple patient types and is difficult to sort out. Analyze the dissections separately. Analyze the leaflet extensions and leaflet repairs separately. Try to learn what is working well and then share it with the Thoracic community.

◆ I have several difficulties with the paper.

First the title is erroneous - this is not a novel technique. At best, it is a novel combination of previously published techniques. The annular correction is virtually identical to the David II procedure annular correction. The leaflet repairs, extensions, etc. have all been described by Duran, Angel, Cosgrove, etc. The STJ fixation/reduction has been discussed by many authors and their technique is the same as the standard four layer dissection repair.

As such I do not find this a novel? technique.



My biggest concern with your technique is that the native tissue at the level of the sinuses is left intact which in previous studies has been shown to lead to subsequent dilation and recurrent root aneurysm +/-AI.

As stated above there does appear to be a trend towards increasing AI by the presented Echo data in this paper. One or two year data would be more helpful.



Thank You for your attention



