SCDU DI CARDIOCHIRURGIA
Università degli Studi di Torino
Ospedale S. Giovanni Battista
Direttore: Prof. Mauro Rinaldi

Minimally invasive aortic valve surgery: new solutions to old problems.

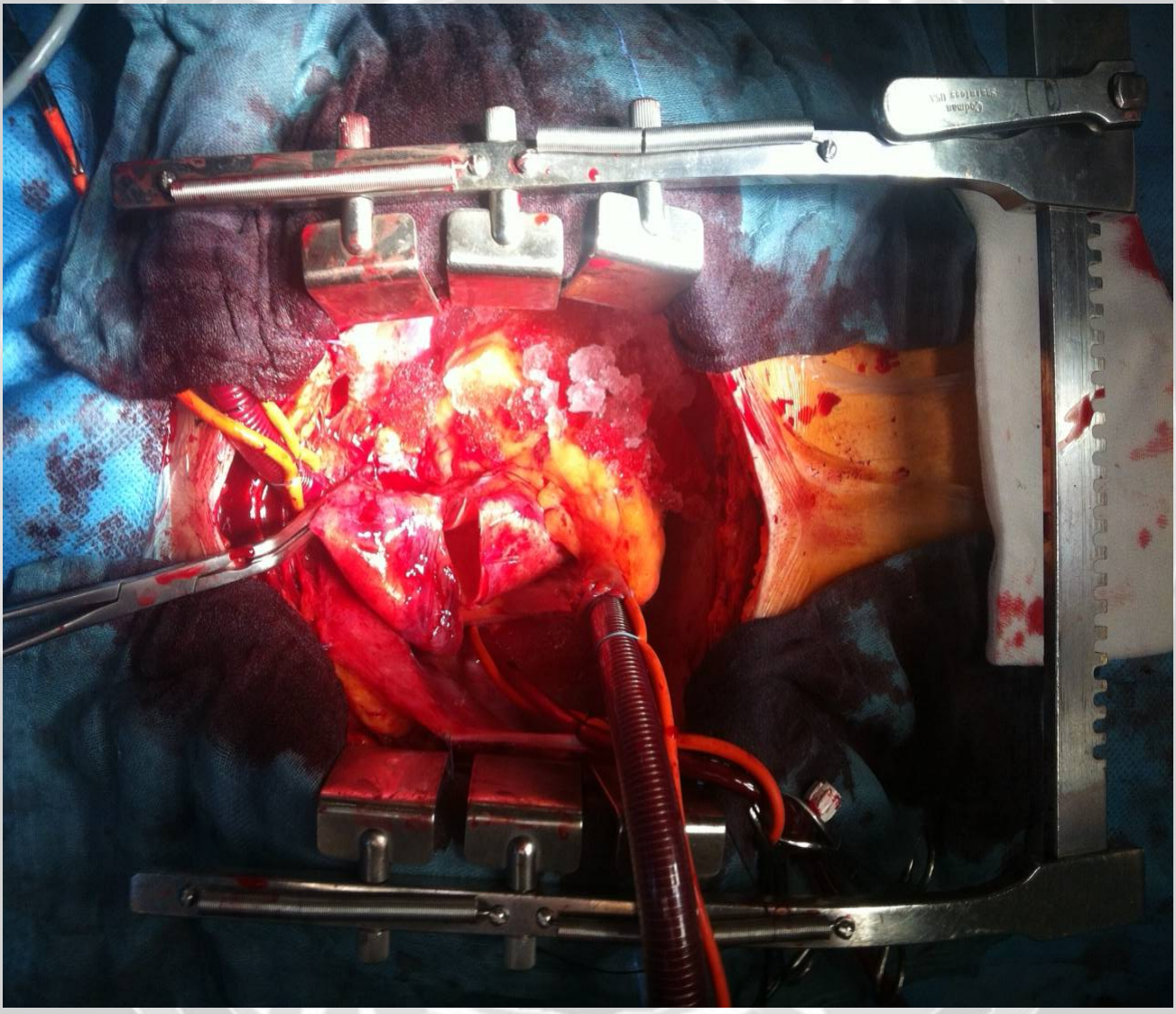
Prof. Mauro Rinaldi

Standard approach to Aortic Stenosis

	Class	Level[b]	Ref[c]
AVR is indicated in patients with severe AS and any symptoms related to AS.	I	B	12, 89, 94
AVR is indicated in patients with severe AS undergoing CABG, surgery of the ascending aorta or another valve.	I	C	
AVR is indicated in asymptomatic patients with severe AS and systolic LV dysfunction (LVEF <50%) not due to another cause.	I	C	
AVR is indicated in asymptomatic patients with severe AS and abnormal exercise test showing symptoms on exercise clearly related to AS.	I	C	
AVR should be considered in high risk patients with severe symptomatic AS who are suitable for TAVI, but in whom surgery is favoured by a 'heart team' based on the individual risk profile and anatomic suitability.	IIa	B	97
AVR should be considered in asymptomatic patients with severe AS and abnormal exercise test showing fall in blood pressure below baseline.	IIa	C	
AVR should be considered in patients with moderate AS[d] undergoing CABG, surgery of the ascending aorta or another valve.	IIa	C	
AVR should be considered in symptomatic patients with low flow, low gradient (<40 mmHg) AS with normal EF only after careful confirmation of severe AS.[e]	IIa	C	
AVR should be considered in symptomatic patients with severe AS, low flow, low gradient with reduced EF, and evidence of flow reserve.[f]	IIa	C	
AVR should be considered in asymptomatic patients, with normal EF and none of the above mentioned exercise test abnormalities, if the surgical risk is low, and one or more of the following findings is present: • Very severe AS defined by a peak transvalvular velocity >5.5 m/s or, • Severe valve calcification and a rate of peak transvalvular velocity progression ≥0.3 m/s per year.	IIa	C	
AVR may be considered in symptomatic patients with severe AS low flow, low gradient, and LV dysfunction without flow reserve.[f]	IIb	C	
AVR may be considered in asymptomatic patients with severe AS, normal EF and none of the above mentioned exercise test abnormalities, if surgical risk is low, and one or more of the following findings is present: • Markedly elevated natriuretic peptide levels confirmed by repeated measurements and without other explanations • Increase of mean pressure gradient with exercise by >20 mmHg • Excessive LV hypertrophy in the absence of hypertension.	IIb	C	

Full sternotomy and conventional CPB

ESC Guidelines - European Heart Journal 2012;33,2451–2496



Isolated aortic valve replacement in North America comprising 108,687 patients in 10 years: Changes in risks, valve types, and outcomes in the Society of Thoracic Surgeons National Database

James M. Brown, MD,[a] Sean M. O'Brien, PhD,[b] Changfu Wu, PhD,[a] Jo Ann H. Sikora, CRNP,[a] Bartley P. Griffith, MD,[a] and James S. Gammie, MD[a]

Changes in patients' characteristics

• Age > 70 yrs	+10%	<0.001
• CRF	+36%	<0.001
• BMI>30	+38%	<0.001
• CVA	+64%	<0.001
• Diabetes	+65%	<0.001
• COPD	+218%	<0.001

➔ Elderly population

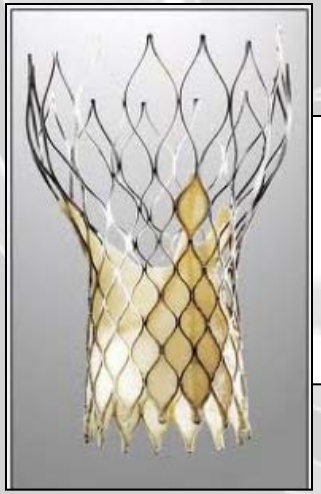
➔ Increased incidence of co-morbidities

Increased number of high risk AVR

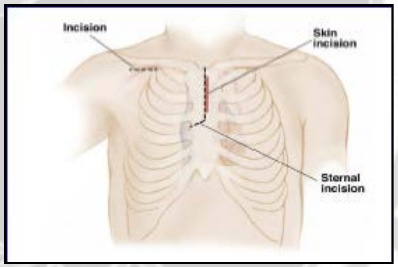
J Thorac Cardiovasc Surg 2009;137:82-90

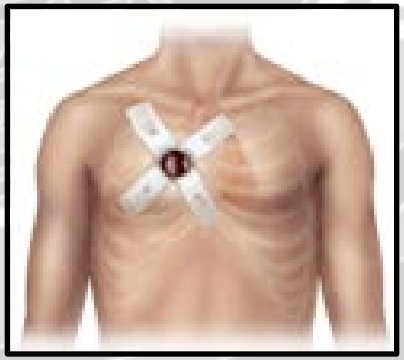
Need for less invasive approaches

TAVI

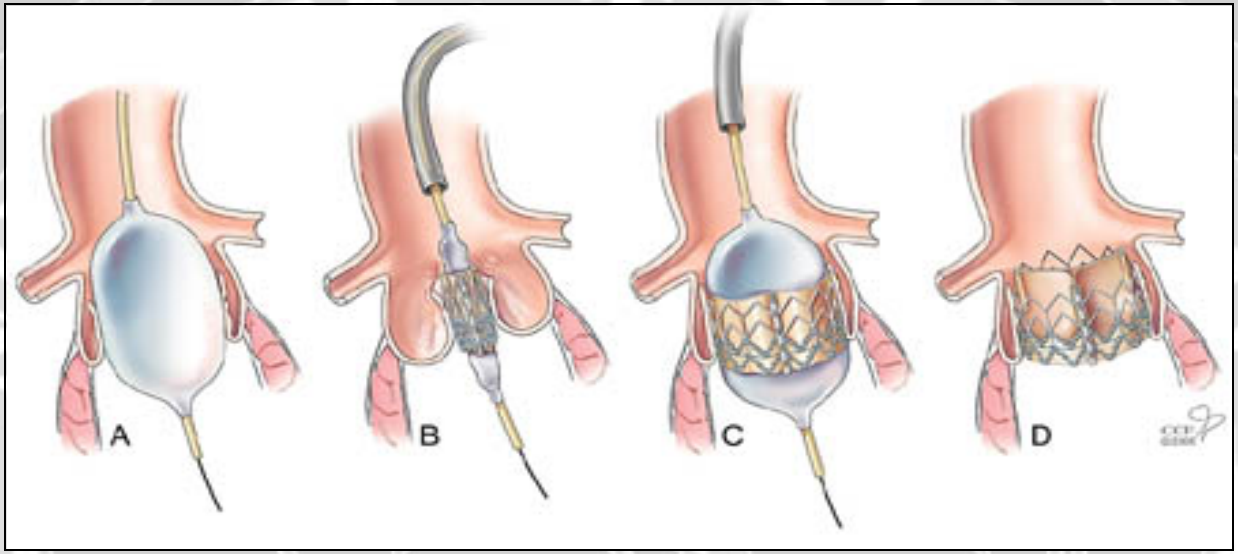


MI-AVR





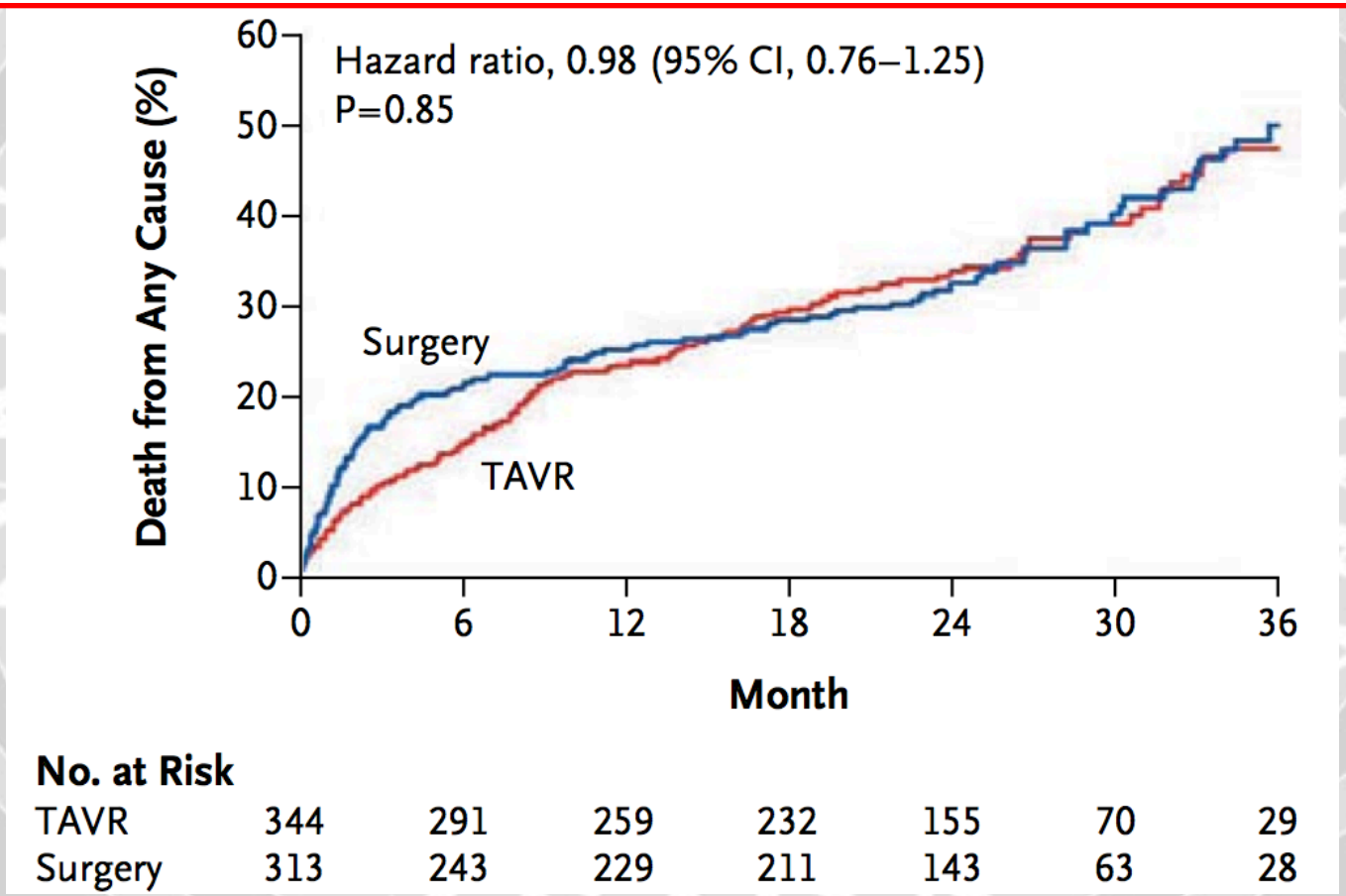
Transcatheter Aortic Valve Implant



- High risk population (elderly pts, ↑co-morbidities);
- HEART-team;
- Is starting to impact on the number of pts referred for conventional AVR;
- Pts may prefer less invasive procedures, even if less effective than more invasive gold standard;
- Costs?

TAVI vs Conventional AVR

Survival



Two-Year Outcomes after Transcatheter or Surgical Aortic-Valve Replacement

Susheel K. Kodali, M.D., Mathew R. Williams, M.D., Craig R. Smith, M.D.,

N Engl J Med 2012;366:168695.

PARTNER Trial®
Cohort A

TAVI vs Conventional AVR
Stroke and Vascular Complications

Table 1. Clinical Outcomes at 1 Year and 2 Years with TAVR or Surgery (Intention-to-Treat Population).*

Outcome	1 Year			2 Years		
	Surgery (N=351)	TAVR (N=348)	P Value†	Surgery (N=351)	TAVR (N=348)	P Value†
	no. of patients (%)			*no. of patients (%)*		
Death						
From any cause	89 (26.8)	84 (24.3)	0.45	114 (35.0)	116 (33.9)	0.78
From cardiovascular causes	40 (13.0)	47 (14.3)	0.63	59 (20.5)	67 (21.4)	0.80
Repeat hospitalization‡	51 (17.7)	59 (18.6)	0.78	60 (21.7)	74 (24.7)	0.41
Death from any cause or repeat hospitalization‡	125 (37.7)	121 (34.9)	0.45	152 (46.5)	159 (46.6)	0.99
Stroke or TIA§						
All	13 (4.3)	28 (8.7)	0.03	18 (6.5)	34 (11.2)	0.05
Stroke	10 (3.2)	20 (6.0)	0.08	14 (4.9)	24 (7.7)	0.17
TIA	4 (1.5)	8 (2.6)	0.32	5 (2.0)	10 (3.6)	0.26
Death from any cause or stroke	95 (28.6)	95 (27.4)	0.74	119 (36.4)	127 (37.1)	0.85
Myocardial infarction	2 (0.6)	0	0.16	4 (1.5)	0	0.05
Major vascular complication¶	13 (3.8)	39 (11.3)	<0.001	13 (3.8)	40 (11.6)	<0.001
Major bleeding‖	88 (26.7)	52 (15.7)	<0.001	95 (29.5)	60 (19.0)	0.002
Endocarditis	3 (1.0)	2 (0.6)	0.63	3 (1.0)	4 (1.5)	0.61
Renal failure**	20 (6.5)	18 (5.4)	0.57	21 (6.9)	20 (6.2)	0.75
New pacemaker	16 (5.0)	21 (6.4)	0.44	19 (6.4)	23 (7.2)	0.69
SVD requiring surgical replacement	0	0		0	0	

Two-Year Outcomes after Transcatheter or Surgical Aortic-Valve Replacement

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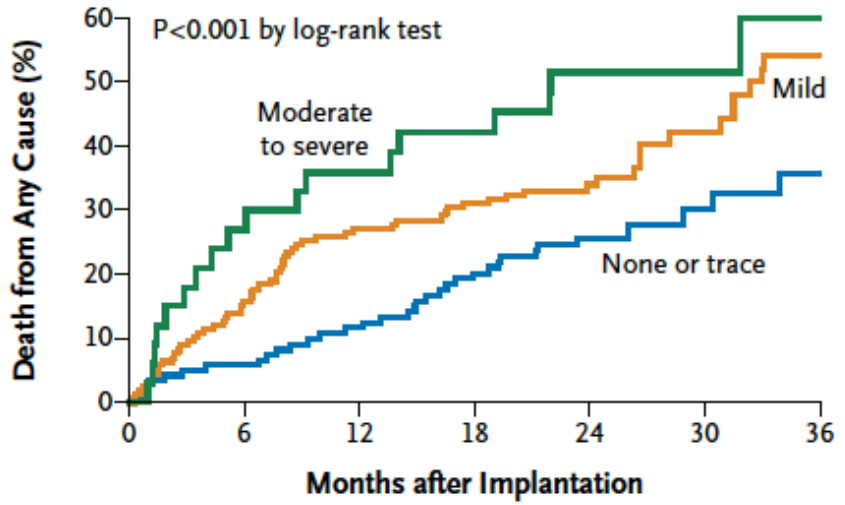
N Engl J Med 2012;366:168695.

PARTNER Trial® Cohort A

TAVI vs Conventional AVR
Residual Aortic Regurgitation

Moderate or severe paravalvular aortic regurgitation was more common after TAVR than after surgical replacement at both 1 and 2 years (7.0% vs. 1.9% at 1 year, and 6.9% vs. 0.9% at 2 years; P<0.001 for both comparisons).

D Severity of Total Aortic Regurgitation: None or Trace, Mild, or Moderate to Severe



No. at Risk

None or trace	125	117	108	95	64	29	10
Mild	162	136	118	109	70	31	15
Moderate to severe	34	25	22	19	15	6	2

Two-Year Outcomes after Transcatheter or Surgical Aortic-Valve Replacement

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N Engl J Med 2012;366:168695.

PARTNER Trial® Cohort A

Ministernotomy AVR

BMJ open accessible medical research

2011; 1(2): e000266

Mini-sternotomy for aortic valve replacement reduces the length of stay in the cardiac intensive care unit: meta-analysis of randomised controlled trials

E Khoshbin, S Prayaga, J Kinsella, F W H Sutherland

Table 1 Study characteristics

Study	Moustafa *et al*, 2007[3]	Dogan *et al*, 2003[4]	Bonacchi *et al*, 2002[5]	Aris *et al*, 1999[6]
Methods	PRCT	PRCT	PRCT	PRCT
No of participants	30+30=60	20+20=40	40+40=80	20+20=40
Mean age in years (full/mini)	23.8/22.9	64.3/65.7	62.6/64.0	62.2/66.5
Sex M:F (full/mini)	15:15/16:14	11:9/9:11	–	–
Operation	Isolated AVR	Isolated AVR	Isolated AVR	Isolated AVR
Interventions	Full sternotomy vs L-shaped mini-sternotomy Pain management with tenoxicam	Complete sternotomy vs L-shaped mini-sternotomy	Standard sternotomy vs C or L-shaped mini-sternotomy	Median sternotomy vs C or L-shaped mini-sternotomy Pain management with metamizol
Outcomes	Duration of ventilation Postop blood loss Length of ICU stay Pulmonary function Analgesic requirement Length of hospital stay Cross-clamp time Bypass time Operation time Survival to discharge	Duration of ventilation Postop blood loss Length of ICU stay Pulmonary function. – Length of hospital stay Cross-clamp time Bypass time Operation time Survival to discharge	Duration of ventilation Postop blood loss Length of ICU stay Pulmonary function Analgesic requirement Length of hospital stay Cross-clamp time Bypass time Operation time Survival to discharge	Duration of ventilation Postop blood loss Length of ICU stay Pulmonary function – Length of hospital stay Cross-clamp time Bypass time Operation time Survival to discharge

AVR, aortic valve replacement; ICU, intensive care unit; PRCT, prospective randomised controlled trial.

Ministernotomy AVR

Minimal Access Aortic Valve Replacement: Is It Worth It?

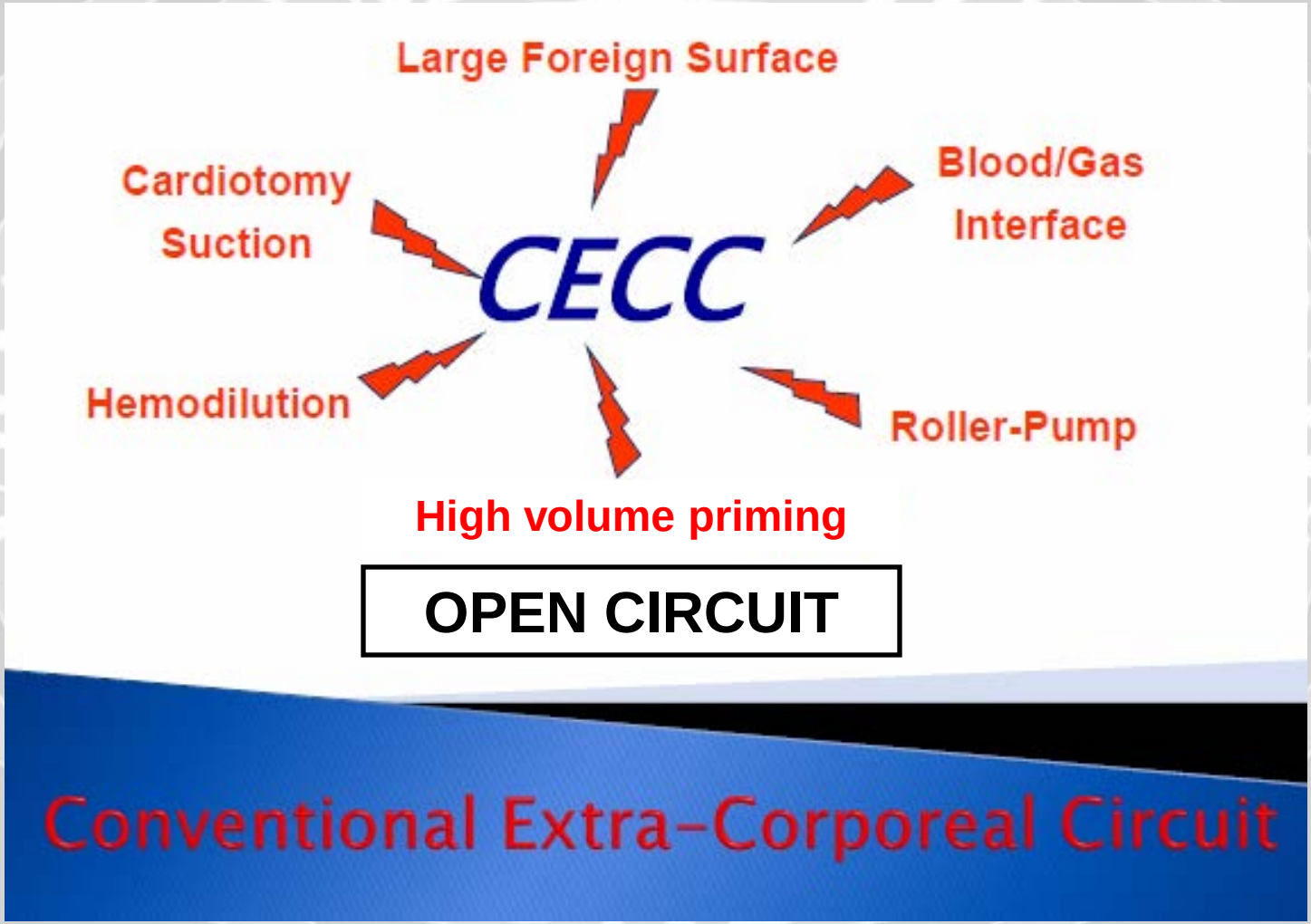
Bari Murtuza, PhD, FRCS, John R. Pepper, FRCS, Rex DeL Stanbridge, FRCS, Catherine Jones, BSc, MBBS, Christopher Rao, MBBS, Ara Darzi, KBE, FRCS, and Thanos Athanasiou, PhD, FETCS

Departments of Cardiothoracic Surgery and Surgical Oncology and Technology, St. Mary's Hospital, Faculty of Medicine, Imperial College, and Department of Cardiothoracic Surgery, Royal Brompton Hospital, Faculty of Medicine, Imperial College, London, England

(Ann Thorac Surg 2008;85:1121–31)

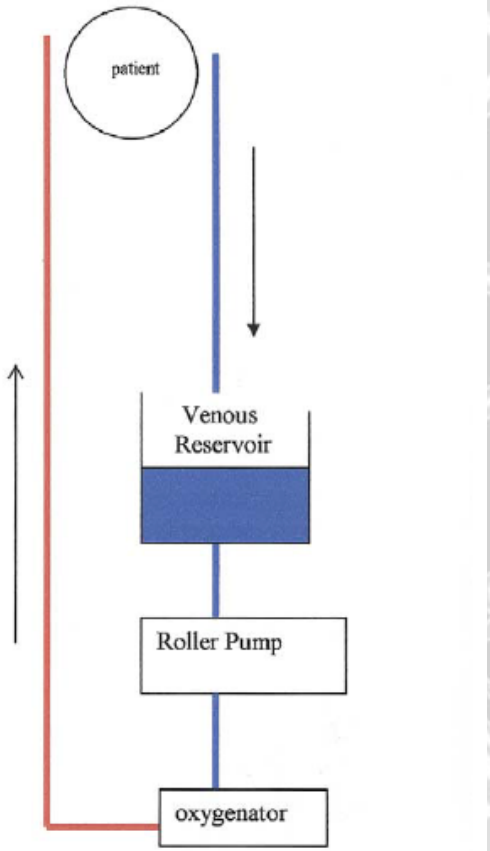
- Smaller incision, better cosmetics;
- Less pain and trauma;
- Less morbidity and faster recovery (?).

From CECC to MECC

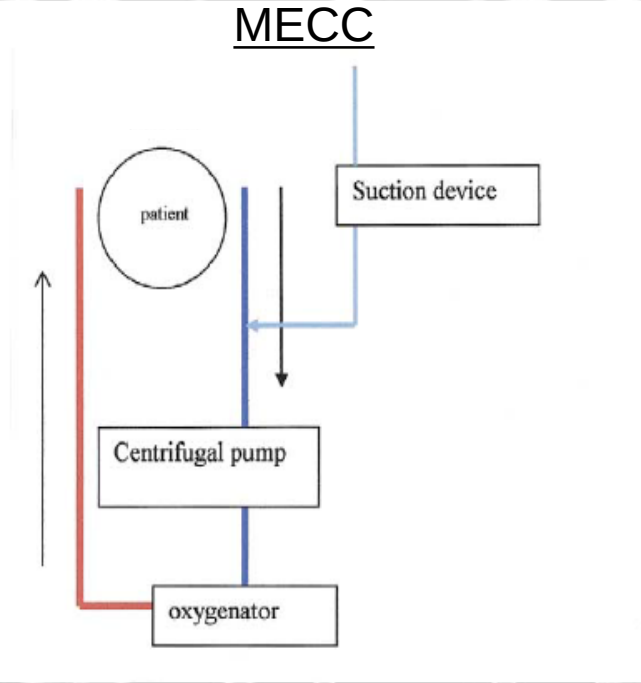


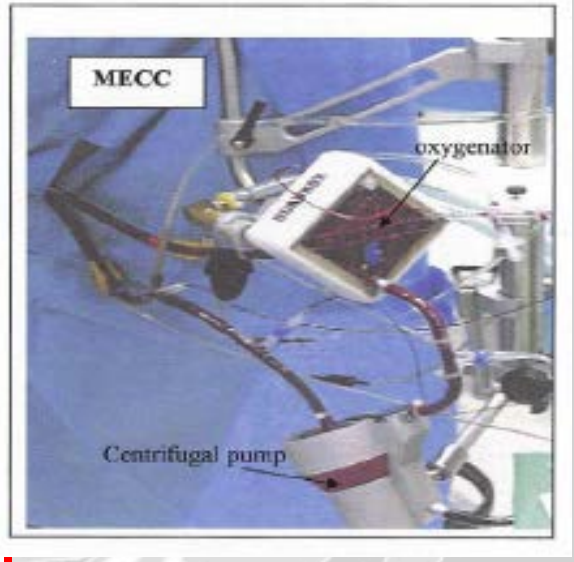
Minimal Extracorporeal Circulation (MECC)

Standard CPB



MECC

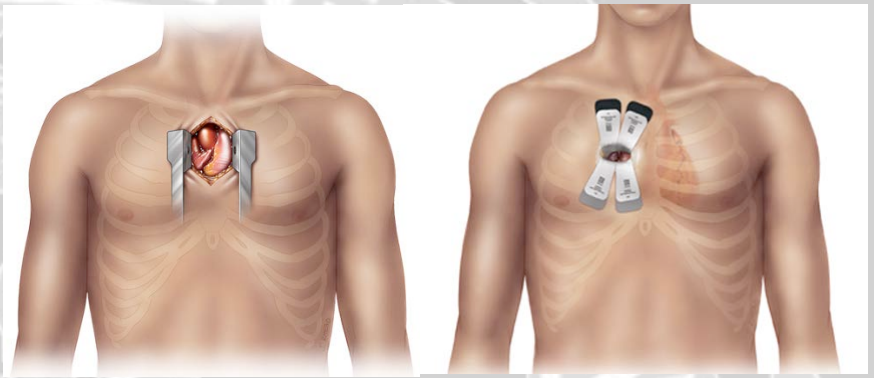




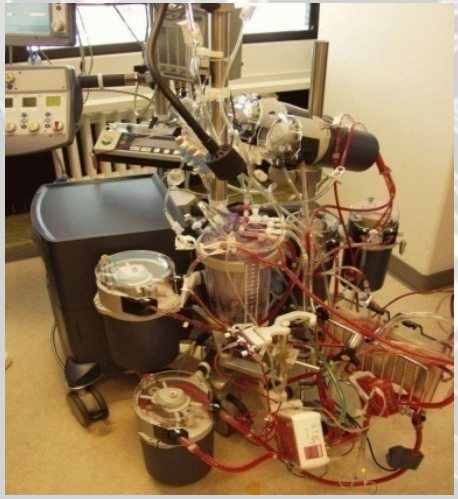
- Closed circuit (no blood-air contact);
- No reservoir;
- Heparine coated tubing.

Minimally invasive AVR

From **sternotomy**…



…to **MINIsternotomy**
or **MINIthoracotomy**



From **Conventional CPB**…

…to **MECC**

Minimal Access Aortic Valve Replacement Using a Minimal Extracorporeal Circulatory System

Alaadin Yilmaz, MD, Atiq Rehman, MD, Uday Sonker, MD, and Geoffrey T. L. Kloppenburg, MD

Department of Cardiothoracic Surgery, St. Antonius Hospital, Nieuwegein, the Netherlands; and Department of Cardiovascular Surgery, Magnolia Regional Health Center, Corinth, Mississippi

(Ann Thorac Surg 2009;87:720–5)

- 50 pts underwent MI-AVR with MECC;
- ***Femoral Artery Cannulation;***
- Groin venous cannulation/pulmonary artery venting.

Minimal Access Aortic Valve Replacement using MECC is feasible and provides excellent clinical and cosmetic results.

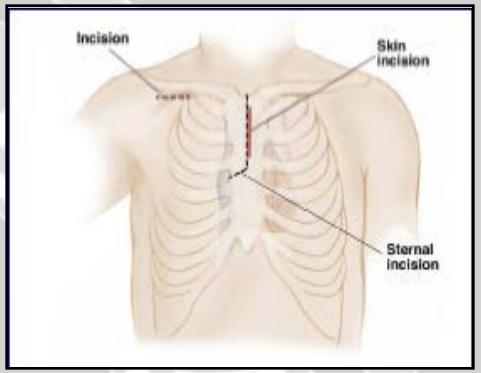
Table 2. Postoperative Course and Complications

Hemoglobin:	
Preoperative	13.5 ± 1.64 g/dL
Postoperative	11.3 ± 1.22 g/dL
Total transfusion requirement:	
Intraoperative	
Packed red blood cells	1
Fresh frozen plasma	0
Platelets	0
Postoperative	
Packed red blood cells	15 (0.30 per patient)
Fresh frozen plasma	8 (0.16 per patient)
Platelets	3 (0.06 per patient)
Length of stay on ICU	2.3 ± 1.6 days
Mean ventilation time	488 ± 315 minutes
Blood loss	372 ± 170 cc
Patients with new rhythm abnormalities	8
Atrial fibrillation	7
Complete heart block	1
Pneumothorax (requiring tube thoracostomy)	1
Superficial wound infection	1
Urinary tract infection	1
Neurologic deficit	1
Mediastinal bleeding requiring reexploration	1
One month mortality	0
Stroke/CVA	0
Renal failure	0
Length of stay in hospital	5.7 ± 3.7 days

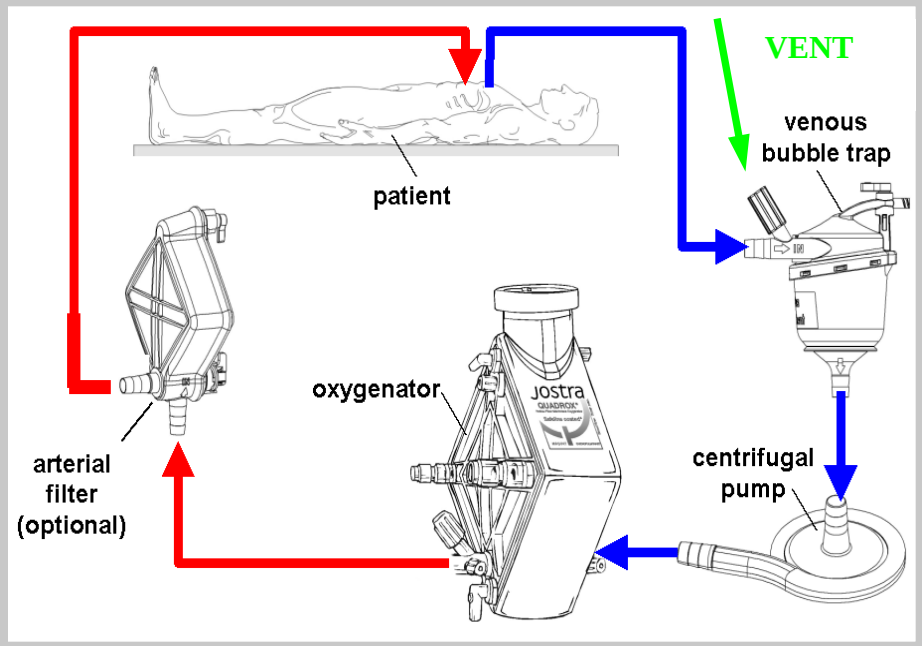
CVA = cerebrovascular accident; ICU = intensive care unit.

MI-AVR with MECC

University Hospital of Turin
Surgical Technique



- ***Direct Aortic Cannulation*** (antegrade flow);
- Groin venous cannulation (minimizes risk of air);
- Pulmonary artery venting;
- Bubble trap;
- Blood cardioplegia;
- Antegrade/Retrograde priming;
- External defib pads;
- CO_2 flooding of the surgical field;
- Aortic venting for de-airing;
- Use of TEE in all patients.



MI-AVR with MECC

MINI-STERNOTOMY: introduced for isolated aortic valve surgery at *Città della Salute e della Scienza* from 2006

From November 2012 MINI-STERNOTOMY + MECC (MI-AVR) in the setting of:

- **Prospective randomized clinical trial VS conventional surgery ➔ evaluation of organ function and systemic inflammatory response**
  (22 patients enrolled)

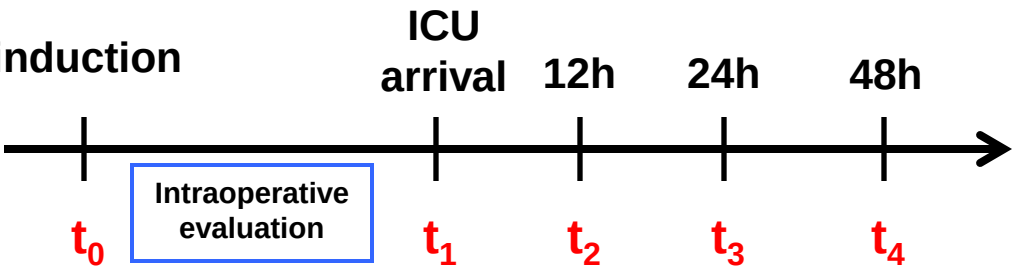
- **High risk population excluded from randomization (COPD, coagulopathy, etc) ➔ Registry**
  (14 patients)

Local Ethical Committee approval

Minimally invasive AVR: Randomised study©

INCLUSION CRITERIA

Isolated aortic stenosis with surgical indication (AHA-ESC Guidelines)



Carefull clinical/instrumental/laboratory monitoring:

- **Haemodilution;**
- **Organ function;**
- **Inflammatory panel (IL-1, IL-6, IL-8, IL-10, TNFα, CRP).**

EXCLUSION CRITERIA

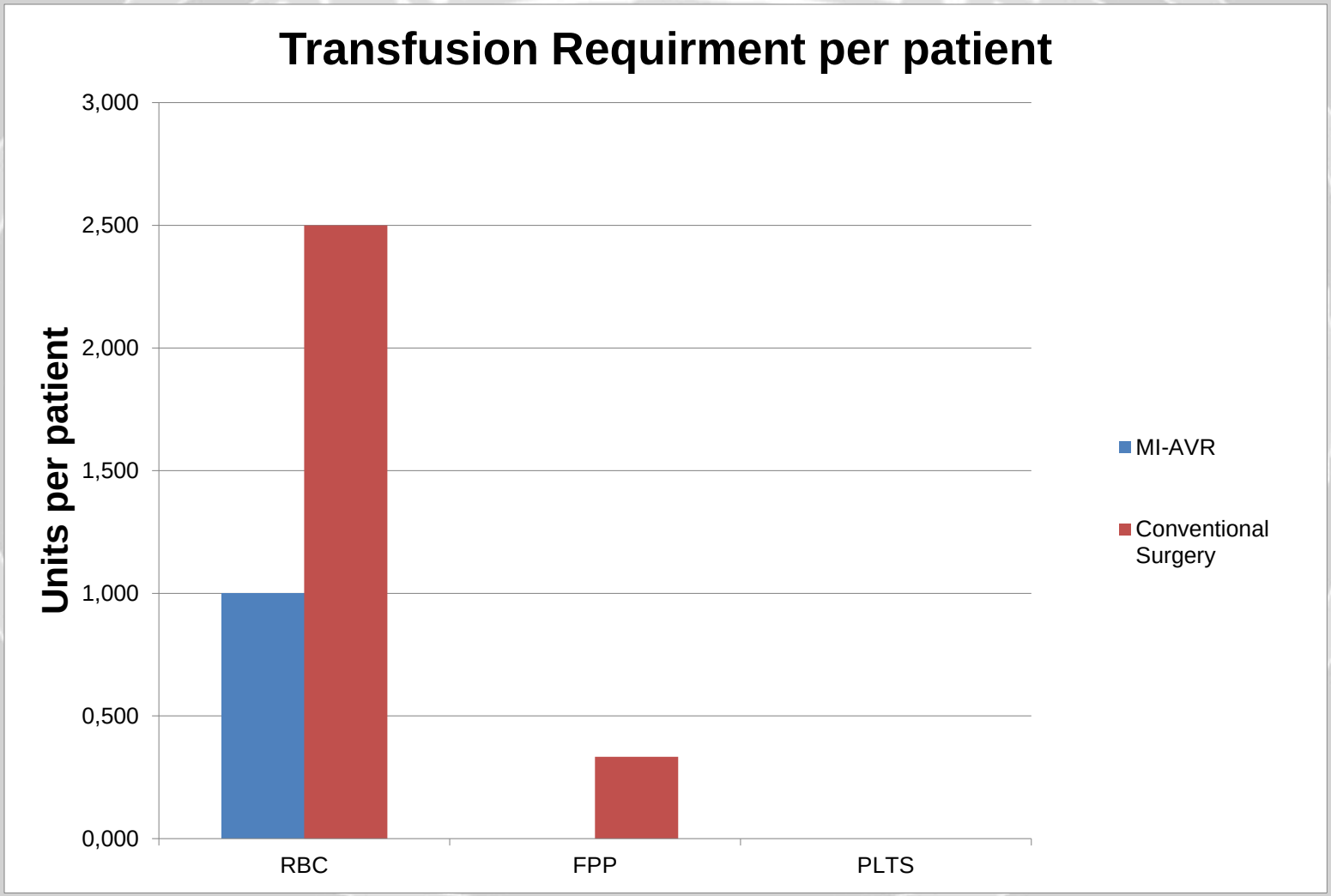
Emergent status
Active endocarditis
Porcelain aorta
Redo
Concomitant Heart Failure
COPD
Coagulopathy/thrombocytopenia
Anemia
Anti-PLTS therapy
Autoimmune/inflammatory disease
CRF
Hepatophaty
EF < 50%
Corticosteroids
Recent MI
History of CVA

Minimally invasive AVR with MECC: Randomized study©

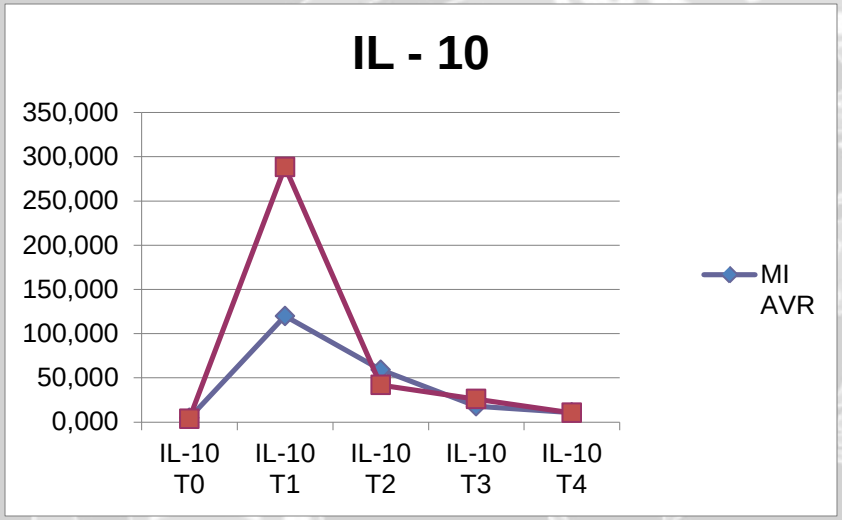
Pts Charachteristics	MI-AVR MECC N° : 10	Conventional AVR N° : 12
Age	75.8 ± 3.9	72.8 ± 10.3
Sex (M/F)	5/5	8/4
EuroSCORE add log	 6.4 ± 0.9 5.7 ± 2.1	 6.0 ± 2.9 5.7 ± 2.4

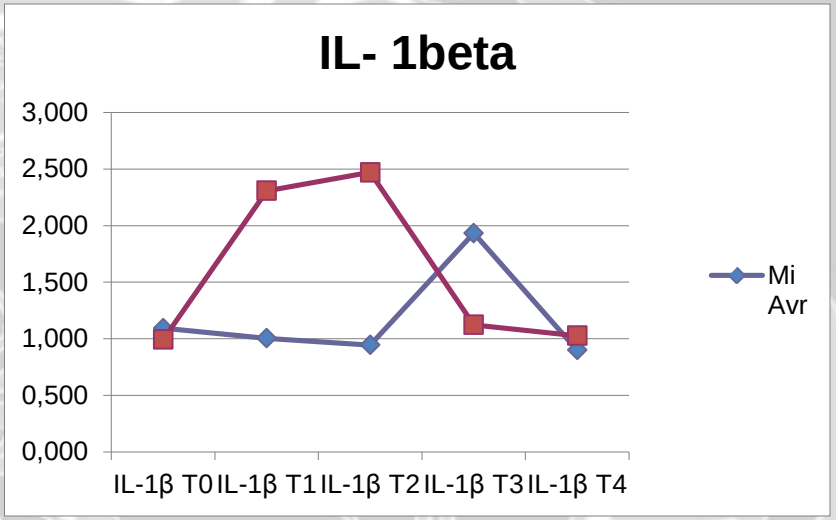
Preliminary Results	MI-AVR MECC N° : 10	Conventional AVR N° : 12
MACCE	0	0
In-hospital 30-day mortality	0	0
Re-opening for bleeding	0	1/12 (8.3%)

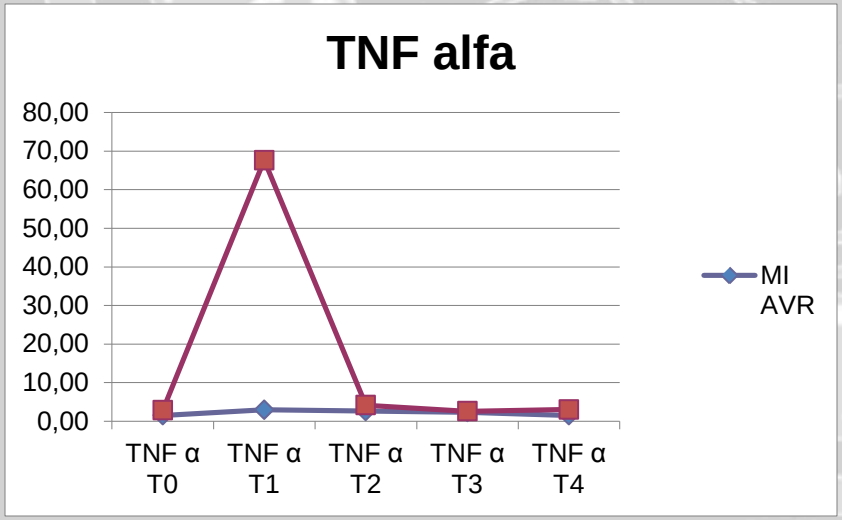
Minimally invasive AVR: Randomised study©

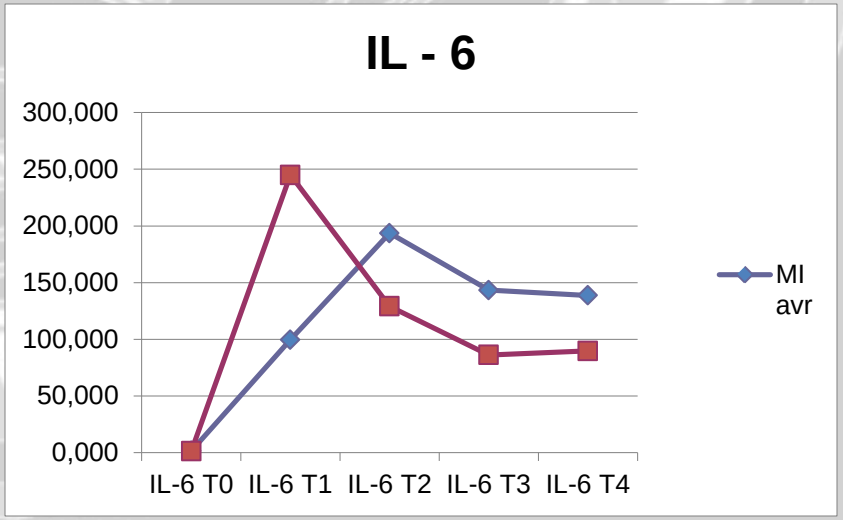


Minimally invasive AVR: Randomised study©









Minimally invasive AVR with MECC: Registry©

Pts Charachteristics	MI-AVR MECC N° : 14
Age	76.8 ± 7.4
Sex (M/F)	9/5
Severe COPD	6/14 (43.1%)
BMI>30	2/14 (14.3%)
Autoimmune / Inflammatory disease	3/14 (21.4%)
Coagulopathy	3/14 (21.4%)
EuroSCORE add log	 8.1 ± 1.3 9.8 ± 1.1

Preliminary Results	MI-AVR MECC N° : 10
Conversion to conventional AVR	1/14 (7.1%)
In-hospital 30-day mortality	0
Re-opening for bleeding	0

Sutureless and rapid deployment prosthesis

A translation of knowledge gained from the performance of TAVI combined with decades of experience of conventional AVR surgery.

From **conventional prosthesis**…

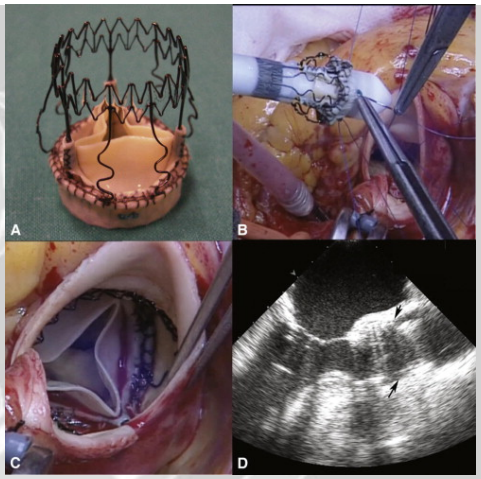
…to **sutureless and rapid deployment prosthesis**

Sutureless aortic valve replacement as an alternative treatment for patients belonging to the "gray zone" between transcatheter aortic valve implantation and conventional surgery: A propensity-matched, multicenter analysis

Augusto D'Onofrio, MD,[a] Antonio Messina, MD,[b] Roberto Lorusso, MD,[c] Ottavio R. Alfieri, MD,[d] Melissa Fusari, MD,[e] Paolo Rubino, MD,[f] Mauro Rinaldi, MD,[g] Roberto Di Bartolomeo, MD,[h] Mattia Glauber, MD,[i] Giovanni Troise, MD,[b] and Gino Gerosa, MD[a]

(J Thorac Cardiovasc Surg 2012;144:1010-8)

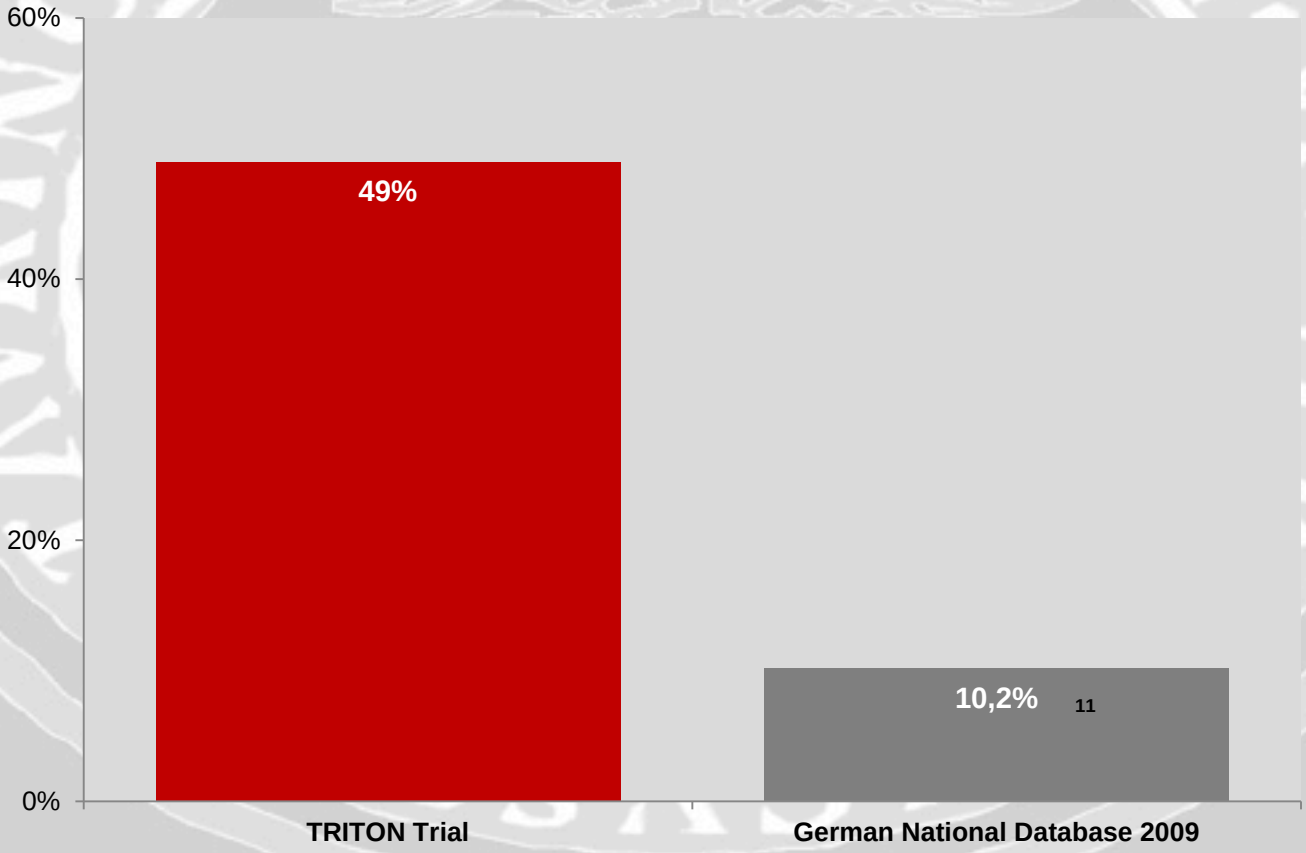
Preliminary experience with sutureless AVR in patients at high risk for conventional surgery



Sutureless-AVR is as safe and effective as TA-TAVI and is associated with a lower rate of postprocedural paravalvular leak.

Greater use of small incision approaches

The TRITON Trial showed markedly increased rates of small incision usage compared to a similar cohort of isolated AVR patients in the German National Database for 2009



Source: Kocher A et al. One-year outcomes of the Surgical Treatment of Aortic Stenosis With a Next Generation Surgical Aortic Valve (TRITON) trial: A prospective multicenter study of rapid-deployment aortic valve replacement with the EDWARDS INTUITY Valve System. *J Thorac Cardiovasc Surg* 2013 Jan;145(1):110-5

Towards the surgical “gold” standard of MI-AVR in high risk patients

MI-AVR combining MECC and Sutureless Aortic Valves:

-To reduce significantly cross clamp and perfusion time;

-To increase surgeons acceptance and promote wide spread of MI-AVR.

Especially in the setting of: Small Aortic Annulus and Poor LV function patients.

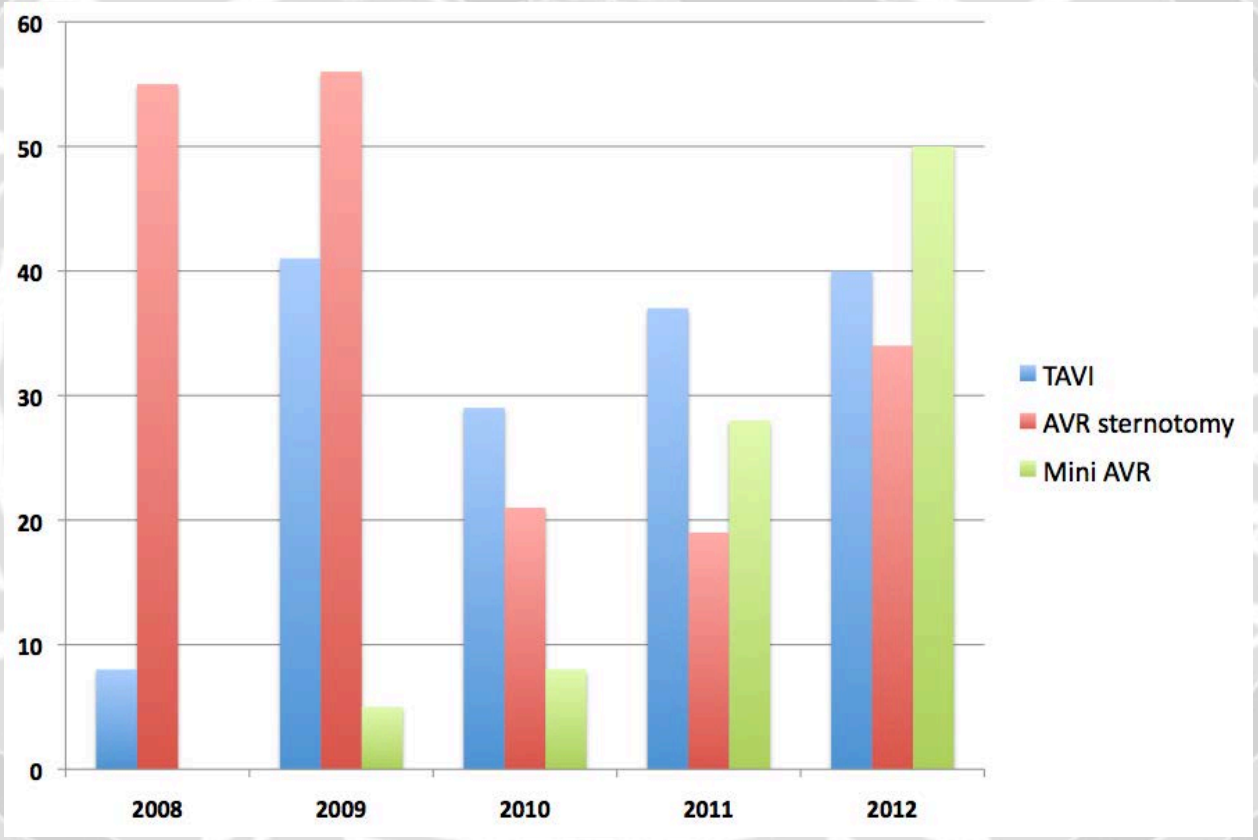
Long term benefits and cost-effectiveness ➔ use under appropriate trial conditions.

Mi AVR
Conclusion

- The “TAVI era” has stimulated surgeons, industries and patients to proceed towards less invasive operations
- The “new” discovery of mini-invasive surgical approaches, the introduction of miniaturized ECC and sutureless valves has been showed to be able to compete with TAVI in the “grey zone”
- TAVI and minimally invasive surgical techniques are totally complementary and should be offered the patient at the same time, in the same center

Procedures for Lone Aortic Valve Stenosis

Città della Salute e della Scienza di Torino 2008-12



Ministernotomy AVR is already an estabilished procedure in our Instiution and is challenging conventional AVR.