# Does minimally invasive aortic replacement reduce risk of surgery?

### **Dr. MAURO DEL GIGLIO**

Chief of the Department of Cardio-Vascular Surgery Maria Cecilia Hospital – Cotignola (RA)



### Suitability of INDICATIONS and TREATMENTS



Rome, Italy

Medical Journals have become the main marketing tools of the pharmaceutical industry







# NOWADAYS

### **Surgery Purpose:**

- Less invasivity
  - Lower the risk
  - Increase toleration
- Customization
  - Anatomy
  - Comorbidities
  - Patients own will









## **OPERATIVE RISKS**

Comorbid **Operative risks** ity - Mortality - Morbidity • Early LV Age frailty • Late function Advantages Survival Quality of life Valve disease





# **SCENERY IN PROGRESS**

- Age, increase of life expectancy
- Prospectives
  - Quality vs longevity
  - Productivity
  - Phisical aspect
- Information
  - More aware patients
  - Referral pattern
- Limited resources and costs
   limitation







## **INDUSTRY INTERESTS**



### **EUR 1,061 BILLIONS**





# **Definition of Minimally Invasive Surgery**

### Cleveland Clinic

"Minimally invasive cardiac surgery (MICS) allows access to the heart, its valves and vessels through small incisions, sometimes using specialized surgical instruments."

For valve replacement or repair, surgeons can make one or two 3 - 4 inch (7-10 cm) incisions instead of the 6 - 8 inch (16-20 cm) incision required for traditional heart surgery.

### The Society of Thoracic Surgeons

"Any procedure that has not been performed with a full sternotomy and cardiopulmonary bypass support. All other procedures, on or off pump with a small incision or off pump with a full sternotomy are considered minimally invasive."







## **Definition of Minimally Invasive Surgery**

At least one of these characteristics:

- Short operating time (including cardiopulmonary bypass and cross clamp time).
- Small incision, avoiding the full sternotomy







# Conventional and minimally invasive incisions







# **Upper Hemisternotomy**







## **UPPER "J" MINI-STERNOTOMY**







### **Upper Hemisternotomy vs Full Sternotomy**

# Minimal invasive aortic valve replacement surgery is associated with improved survival: a propensity-matched comparison<sup>†</sup>

Denis R. Merk<sup>a,\*</sup>, Sven Lehmann<sup>a,\*</sup>, David M. Holzhey<sup>a</sup>, Pascal Dohmen<sup>a</sup>, Pascal Candolfi<sup>b</sup>, Martin Misfeld<sup>a</sup>, Friedrich W. Mohr<sup>a</sup> and Michael A. Borger<sup>a,\*</sup>

### CONCLUSIONS

Table 4: Early postoperative outcomes in matched patients

MIS is associated with excellent early and long-term survival when compared with conventional AVR surgery. Despite our observed longer myocardial ischaemic times and a higher re-exploration rate for bleeding, MIS AVR can be performed safely with very good early and long-term results that are at least equivalent to those achieved through a conventional sternotomy approach.

Variables	MIS (n = 477)	FS ( <i>n</i> = 477)	P-value
Low cardiac output	3/477 (0.6%)	8/477 (1.7%)	0.13
Intra-aortic balloon pump	2/477 (0.4%)	10/477 (2.1%)	0.021
Extracorporeal membrane oxygenation	1/477 (0.2%)	4/477 (0.8%)	0.18
Myocardial infarction	1/477 (0.2%)	3/477 (0.6%)	0.32
Cardiac arrhythmia	159/477 (33.3%)	171/477 (35.8%)	0.38
Re-exploration	20/477 (4.2%)	7/477 (1.5%)	0.009
Red blood cell transfusion >3	134/477 (28.1%)	94/477 (19.7%)	0.002
Delirium	28/477 (5.9%)	10/477 (2.1%)	0.003
Cerebrovascular accident	3/441 (0.7%)	9/441 (2.0%)	0.083
Wound infection	0/477 (0%)	0/477 (0%)	-
Dialysis	17/477 (3.6%)	17/477 (3.6%)	1.0
Respiratory failure	32/474 (6.8%)	33/474 (7.0%)	0.90
Ventilation >24 h	30/125 (24.0%)	24/125 (19.2%)	0.36
Reintubation	13/125 (10.4%)	19/125 (15.2%)	0.27
Tracheotomy	7/470 (1.5%)	10/470 (2.1%)	0.47
New pacemaker	20/477 (4.2%)	20/477 (4.2%)	1.0
In-hospital mortality	2/477 (0.4%)	11/477 (2.3%)	0.013
Hospital length of stay	12.9 ± 6.7	12.3 ± 5.6	0.35





European Journal of Cardio-Thoracic Surgery (2014) 1-7 doi:10.1093/ejcts/ezu068



## UPPER "J" MINI-STERNOTOMY Our experience at Maria Cecilia Hospital 2010 – 2014

### 569 PATIENTS

 Age:
 75 (26 - 90)
 55.36% male

 EuroSCORE:
 6 (0 - 18)
 Logistic ES:
 6.19 (0.88 - 77.95)
 REDO:
 30 (5.27%)

Bicuspid valves: 8.61%

 Skin-to-skin time:
 163 (97-370)
 CPB time:
 69 (28-206)
 ACC time:
 59 (24-157)

 Biological prostheses:
 88.4%

### **MORTALITY: 1.99%**

Hospital stay (days): 7 (3-140)

ICU stay (hours): 45 (13-792)







# **Right Mini-thoracotomy**







# **RIGHT ANTERIOR THORACOTOMY (RAT)**

- RAT was first described by Rao and Kumar
- Galloway et al modified the right parasternal approach reported by Cosgrove and Sabikand Cohn but the right parasternal approach has been largely abandoned because of the incidence of chest wall hernia and also because of the incision crossing skin lines.
- transverse sternotomy and partial upper or lower sternotomy have been widely used but still require some form of sternotomy.
- Several small early series using right minithoracotomy have reported favorable results in selected patients.
   Few series >100 patients have been reported.

Aortic Valve Replacement Through Right Minithoracotomy in 306 Consecutive Patients

(Innovations 2010;5:326-330)





Donald D. Glower, MD, Teng Lee, MD, and Bhargavi Desai, BS

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# POSSIBLE BENEFITS OF MINI-THORACOTOMY

- Pain Reduction
- Improved cosmetic results
- Early mobilization, recovery and return to activity
- Reduced ICU and hospital stay
- Less transfusion required and
- Lower risk of bleeding
- Less wound complications
- Improved postoperative pulmonary function
- High psychological acceptance

























### PERICARDIAL STITCHES







### AORTIC PURSE STRINGS









### **RIGHT ATRIUM**

### SUPERIOR PULMONARY VEIN









# AORTIC CANNULATION







### **RIGHT ATRIUM CANNULATION**









### AORTIC CROSS CLAMPING

















### PROSTHESIS IMPLANTATION

















### **Right Minithoracotomy vs Full Sternotomy**

### Minimally Invasive and Conventional Aortic Valve Replacement: A Propensity Score Analysis

Daniyar Gilmanov, MD, Stefano Bevilacqua, MD, Michele Murzi, MD, Alfredo G. Cerillo, MD, Tommaso Gasbarri, MD, Enkel Kallushi, MD, Antonio Miceli, MD, and Mattia Glauber, MD

Department of Adult Cardiac Surgery, G. Pasquinucci Heart Hospital, Gabriele Monasterio Foundation, Massa, Italy

*Background.* The study aimed to compare the shortterm results of aortic valve replacement through minimally invasive and sternotomy approaches.

*Methods.* This is a retrospective, observational, cohort study of prospectively collected data on 709 patients undergoing isolated primary aortic valve replacement between 2004 and 2011. Of these, 338 were performed through either right anterior minithoracotomy or upper ministernotomy. With propensity score matching, 182 patients (minimally invasive group) were compared with 182 patients in conventional sternotomy (control group).

*Results.* After propensity matching, the 2 groups were comparable in terms of preoperative characteristics. Cardiopulmonary bypass time (117.5 vs 104.1 min, p < 0.0001) and aortic cross-clamping time (83.8 vs 71.3 min, p < 0.0001) were longer in the minimally invasive group, with no difference in length of stay (median 6 vs 5 days, p = 0.43), but shorter assisted ventilation time (median

8 vs 7 hours, p = 0.022). Overall in-hospital mortality was identical between the groups (1.64 vs 1.64%, p = 1.0). No difference in the incidence of major and minor postoperative complications and related morbidity was observed. Minimally invasive aortic valve replacement was associated with a lower incidence of new onset postoperative atrial fibrillation (21% vs 31%, p = 0.04). Reduction of the complication rate was observed. Median transfusion pack per patient was higher in the control group (2 vs 1 units, p = 0.04).

*Conclusions.* Our experience shows that mini-access isolated aortic valve surgery is a reproducible, safe, and effective procedure and reduces assisted ventilation duration, the need for blood product transfusion, and incidence of post-surgery atrial fibrillation.

(Ann Thorac Surg 2013;96:837–43) © 2013 by The Society of Thoracic Surgeons







## **Right Minithoracotomy vs Full Sternotomy**

Table 2. Clinical Outcome of Propensity Matchea Patients			
Variables	CAVR (n = 182)	MIAVR ( $n = 182$ )	P Value
CPB time, minutes	$104.1\pm34.6$	$117.5 \pm 41.9$	< 0.0001
Aortic cross-clamping time, minutes	$71.3\pm27.5$	$83.8\pm28.5$	< 0.0001
In-hospital mortality	3 (1.6)	3 (1.6)	1.0
Assisted ventilation time, hours <sup>a</sup>	8 (6-11)	7 (6–9)	8.022
Assisted ventilation longer than 12 hours	33 (18.1)	23 (12.6)	0.2
Assisted ventilation longer than 24 hours	9 (4.9)	4 (2.2)	0.27
Low cardiac output syndrome	1 (0.5)	2 (1.1)	0.26
New onset of AF	57 (31.3)	39 (21.4)	0.043
Third degree atrioventricular block	2 (1.1)	2 (1.1)	1.0
Permanent CVA (stroke)	4 (2.2)	2 (1.1)	0.69
Transient CVA	1 (0.5)	1 (0.5)	1.0
Hemodialysis	2 (1.1)	3 (1.6)	0.41
Infective complications	5 (2.7)	4 (2.2)	0.28
Pulmonary complications	8 (4.4)	10 (5.5)	0.58
Pleural effusion requested drainage	5 (2.7)	10 (5.5)	0.19
Reexploration for bleeding	11 (6.0)	8 (4.4)	0.63
Revision for other reasons	2 (1.1)	5 (2.7)	0.45
Blood transfusion pack per patient, unit <sup>a</sup>	2 (0-3)	1 (0-2)	0.046
Postoperative in-hospital length of stay, days <sup>a</sup>	6 (5–7)	5 (5-6)	0.43
Postoperative length of stay more than 6 days	53 (29.1)	48 (26.4)	0.62

### Clinical Outcome of Pronoucity Matched Dationt T-11-0

<sup>a</sup> Median value (25th to 75th percentile).

Values are expressed as n (%) unless otherwise specified.

AF = atrial fibrillation;CAVR = conventional aortic valve replacement; dent; MIAVR = minimally invasive aortic valve replacement.

CPB = cardiopulmonary bypass;

CVA = cerebrovascular acci-

Ann Thorac Surg 2013;96:837-43





Number of patients Gender (males) Median age 218 consecutive 122 (55.96%) 75 (range 16-93)

CPB Time (median) ACC Time (median) 60 (range 41-210) → 53.5 (range 41-69) 48 (range 31-134) → 42 (range 31-58)

\* Last 50 patients

Sole absolute contraindication to the approach: left pneumectomy













- MORTALITY: 3 (1.49%)
- Bleeding coming mainly from chest wall requiring reoperation in 4% of the cases without sequelae
- 1 single case of wound infection in a redo pt with porcelain aortic arch not eligible for TAVI
- Paravalvular leaks
  - Two evaluated at intraoperatory TEE and corrected by restarting CBP
  - No PVL at discharge







Table 4 . Outcome 🜲				Article in press
Characteristics	Peripheral Cannulation (N=42)	Central Cannulation (N=164)	Total (N=206)	Article in press
Ventilation time (h)		·		
Mean ± SD	$8 \pm 6$	$9 \pm 12$	$9 \pm 11$	N Pro-
Median (min - max)	6 (0-30)	6 (0-120)	6 (0 - 120)	
ICU stay (h) ♦				
Mean ± SD	$56 \pm 89$	$61 \pm 109$	$60 \pm 105$	
Median (min - max)	40 (15 – 598)	40 (13-1258)	40 (13-1258)	
Discharged alive (%)	42 (100)	161 (98.2)	203 (98.5)	
Discharged to (%)				
Home	22 (52.4)	77 (47)	99 (48.1)	
Rehabilitation	18 (42.9)	81 (49.4)	99 (48.1)	
Other	2 (4.8)	6 (3.6)	8 (3.9)	
Hospital stay (days)				
Mean ± SD	$14.4 \pm 24.4$	$11.7 \pm 8.2$	$12.3 \pm 13.2$	
Median (min - max)	9 (5 – 164)	10 (5-59)	9 (5-164)	

♣ Values display total number of patients reported as mean ± standard deviation and as median (range).

♦ ICU= intensive care unit;

### Aortic valve replacement via right mini-thoracotomy: is it really biologically minimally invasive?



Elisa Mikus MD<sup>1</sup>, Simone Turci MD<sup>2</sup>, Simone Calvi MD<sup>1</sup>, Massimo Ricci MD<sup>2</sup>, Luca Dozza MS,<sup>3</sup> / Mauro Del Giglio MD, PhD<sup>1, 2</sup>.



### Right Minithoracotomy Critiques to the technique...







# **Meta-Analysis**

### A Meta-Analysis of Minimally Invasive Versus Conventional Sternotomy for Aortic Valve Replacement

### Kevin Phan, BS(Adv), Ashleigh Xie, Marco Di Eusanio, MD, PhD, and Tristan D. Yan, MBBS, PhD

The Collaborative Research (CORE) Group, Macquarie University, Sydney, New South Wales, Australia; Cardiovascular Surgery Department, Sant'Orsola-Malpighi Hospital, Bologna University, Bologna, Italy; and Department of Cardiothoracic Surgery, Royal Prince Alfred Hospital, Sydney Medical School, University of Sydney, Sydney, New South Wales, Australia

Minimally invasive aortic valve replacement (AVR) is increasingly used as an alternative to conventional AVR, despite limited randomized evidence available. To assess the evidence base, a systematic search identified 50 comparative studies with a total of 12,786 patients. A metaanalysis demonstrated that minimally invasive AVR is associated with reduced transfusion incidence, intensive care stay, hospitalization, and renal failure, and has a mortality rate that is comparable to conventional AVR. The evidence quality was mostly very low. Given the inadequate statistical power and heterogeneity of available studies, prospective randomized trials are needed to assess the benefits and risks of minimally invasive AVR approaches.

> (Ann Thorac Surg 2014;98:1499–511) © 2014 by The Society of Thoracic Surgeons







# **Meta-Analysis**

Mini         Full           Study or Subgroup         Events         Total         Events         Total         Weight         M           Minithoracotomy         Frazier         1         30         0.9%         1         30         0.9%         1         30         0.9%         1         30         0.9%         1         30         0.7%         1         1         30         0.9%         1         30         0.7%         1         1         1         1         1         1         1         1         1         1         1         1         1         1         1         1	Risk Ratio         Risk Ratio           H, Random, 95% CI         Year           0.88 [0.06, 12.73]         1998           1.00 [0.06, 15.61]         2004           0.71 [0.01, 2.90]         2010           1.45 [0.14, 15.49]         2011           0.20 [0.01, 4.06]         2012           0.30 [0.01, 8.00]         2012           0.13 [0.01, 2.27]         2013           0.02 [0.27, 1.41]         0.41 [0.27, 1.41]	Fig 2. Perioperative mortality in patients undergoing minimally invasive aortic valve replacement (MIAVR) vs conventional aortic valve replacement (CAVR). (M-H = Mantel-Haenszel test.) The solid squares denote the risk ratio and are proportional to the weights used in the meta-analysis. The solid vertical line indicates no effect. The diamond denotes the weighted risk ratio, and the lateral tips of the diamond indicate the associated confidence intervals (CIs). The horizontal lines represent the 95% CIs.	
Bridgewäter 1995         2         14         0         14         0.0%           Swerc 1999         1         60         0         60         0.7%           Machler 1999         1         60         0         60         0.7%           Lu 1996         2         26         2         78         1.9%           Christiansen 1999         0         25         0         25           Aris 1999         0         20         0         19           Charg 1999         0         20         0         19           Charg 1999         0         18         0         16           Earlich 2000         1         46         1         40         0.9%           Defler 2002         0         70         2         70         0.8%           Massello 2002         1         100         1         25         25           Doll 2002         1         40         1         40         0.9%           Datter 2002         10         1         100         1.2%         Bonacchi 2002         10         1         100         1.2%           Bonacchi 2002         1         40         2	0.00 [2.2, 95-61]         1986           1.00 [0.0, 61, 555]         1999           3.00 [0.12, 72.20]         1999           0.01 [0.13, 62.20]         1999           Not estimable         1990           Not estimable         1990           Not estimable         1990           0.02 [0.14, 409]         2002           0.20 [0.14, 409]         2002           0.20 [0.14, 409]         2002           0.20 [0.14, 409]         2002           0.20 [0.15, 5.50]         2003           0.20 [0.06, 15.65]         2003           0.20 [0.06, 15.65]         2003           0.70 [0.18, 1.54]         2004           Not estimable         2004           Not estimable         2004           0.54 [0.02, 1.261]         2006           0.54 [0.02, 1.56]         2006           0.56 [0.05, 5.30]         2007           Not estimable         2009           0.54 [0.05, 4.56]         2009           0.54 [0.05, 4.56]         2009           0.54 [0.		
Johnston 2012         8         832         8         832         7.4%           Bang 2012         0         73         73         0.8%           Paredes 2013         0         83         26         532         0.9%           Mikus 2013         1         38         52         1.4%           Stubtotal (9% Ct)         366         4604         403.6%           Total events         74         163         +464         63.8%           Heterogenetity: Tau' = 0.00; Chir = 12.74, dr = 25 (F = 0.86); I <sup>i</sup> = 0%         +96%; I <sup>i</sup> = 0%         +96%; I <sup>i</sup> = 0%	1 00 [0 38, 265] 2012 0.20 [0.01, 4.10] 2012 0.12 [0.01, 1.45] 2013 0.46 [0.05, 4.22] 2013 0.72 [0.54, 0.97]		(Ann Thorac Surg 2014;98:1499–511) © 2014 by The Society of Thoracic Surgeons
Test for overall effect: Z = 2.18 (P = 0.03)	4014 5007	100.0%	0.01
Total (95% CI)	4014 0007	100.0%	
Heterogeneity: Tau <sup>2</sup> = 0.00; Chi <sup>2</sup> =	= 17.88, df = 37 (P = 1.0	0); I <sup>a</sup> = 0%	
Test for overall effect: Z = 2.27 (P	= 0.02)		Favours MIAVR Favours CAVR

500

\* 🖉

# **Meta-Analysis**

The minimally invasive approach to AVR has advantages of decreased ICU days and hospital stay, which may be attributed to the reduced surgical trauma associated with MIAVR Furthermore, subgroup analysis demonstrated decreased wound infections with minithoracotomy than with ministernotomy and CAVR. These benefits may be translated from the smaller incision, sternum preservation, and integrity of the costal cartilages associated with the minithoracotomy approach. (Ann Thorac Surg 2014;98:1499–511) © 2014 by The Society of Thoracic Surgeons

trauma. Although proponents of CAVR have argued that these advantages of MIAVR are offset by drawbacks of longer operation durations, the current meta-analysis indicates that differences in CPB and cross-clamp durations are, in fact, relatively short (range, 8 to 9 minutes).

In conclusion, current evidence suggests that MIAVR is associated with reduced death, ICU stay, hospitalization, renal failures, transfusions, and pain, but only slightly longer durations of cross-clamping and CPB. Given the paucity of high-quality evidence, a multicenter prospective RCT should be conducted prospectively with adequate power and follow-up duration to measure clinical, resource, and time-related outcomes to definitively assess MIAVR procedures.





### **SUTURELESS**







## **EUROPEAN MARKET TRENDS**







# MINI-STERNOTOMY AORTIC VALVE REOPERATION







### **AORTIC VALVE REOPERATION**







# Redo: UPPER "J" MINI- vs FULL-STERNOTOMY

### Upper 'J' Ministernotomy versus Full Sternotomy: An Easier Approach for Aortic Valve Reoperation

Elisa Mikus, Simone Calvi, Alberto Tripodi, Mauro Lamarra, Mauro Del Giglio

Department of Cardiothoracic and Vascular Surgery, Maria Cecilia Hospital, GVM for Care & Research, ES Health Science Foundation, Cotignola (RA), Italy

The Journal of Heart Valve Disease 2013;22:295-300

Table II: Operative results and early outcome.			
Variable	Mini- sternotomy (r = 38)	Full sternotomy (n = 52)	p-value
CPB time (min) <sup>+</sup>	67.00 (28)	72.00 (47)	0.686
Cross-clamp time (min)+	51.00 (28)	53.50 (28)	0.993
IABP#	0 (0)	1 (1.9)	-
Mechanical ventilation (h)+	6.00 (5)	8.50 (11)	0.027
ICU time (h)+	48.00 (34)	46.25 (46)	0.364
Cerebrovascular accident#	1 (2.6)	1 (1.9)	0.822
Re-exploration for bleeding <sup>#</sup>	3 (7.9)	3 (5.8)	0.690
Postoperative dialysis#	2 (5.3)	4 (7.7)	0.690
Postoperative PM implantation <sup>#</sup>	4 (10.5)	5 (9.6)	0.887
RBC units <sup>+</sup>	2.00 (4)	3.50 (5)	0.485
Platelet units and FFP units <sup>+</sup>	0.00 (0)	0.00 (0)	0.737
Hospital mortality <sup>#</sup>	1 (2.6)	3 (5.8)	0.476

<sup>+</sup>Values are median (interquartile range).

\*Values in parentheses are percentages.

CPB: Cardiopulmonary bypass; FFP: Fresh-frozen plasma; IABP: Intra-aortic balloon pump; ICU: Intensive care unit; PM: Pacemaker; RBC: Red blood cell.







### **AORTIC VALVE REOPERATION**

### Our experience at Maria Cecilia Hospital 06/2007 - 4/2014

Characteristics	Patient Population (N=52)
Age (yr)	
Mean ± SD	$70.7 \pm 12.5$
Median (min - max)	75.5 (30 - 84)
Male sex (%)	30 (57.7)
Body-mass Index	
Mean ± SD	$25.9 \pm 4.6$
Median (min - max)	25.2 (17.5 - 36.7)
Chronic lung disease (%)	9 (17.3)
Renal Failure (%)	6 (11.5)
(creat, >2mg/dl)	
Active Endocarditis	2 (3.8)
EuroSCORE (%)♦	
Mean ± SD	$10.8 \pm 3.2$
Median (min - max)	11 (5 – 22)
Previous CABG (%)	30 (57.7)
CPB time (min) ♣	
Mean ± SD	$72.7 \pm 25.5$
Median (min - max)	65.5 (38 - 144)
Cross-clamp time (min)	
Mean ± SD	56.4 ± 22.7
Median (min - max)	49.0 (31 - 130)
Ventilation time (h)	
Mean ± SD	$23.9 \pm 62.6$
Median (min - max)	7 (3 - 408)
ICU stay (h) 🌢	
Mean ± SD	$84.5 \pm 103.6$
Median (min - max)	48 (20 – 595)
Postoperative myocardial infarction (%)	
Discharged alive (%)	$_{51(98.1)}$ Article in press.









# MINI-STERNOTOMY AORTIC ROOT SURGERY







# **AORTIC ROOT MINI-STERNOTOMY**

State-of-the-art - Cardiac general Ministernotomy approach for surgery of the aortic root and ascending aorta Interactive CardioVascular and Thoracic Surgery 9 (2009) 849-858

Sossio Perrotta».\*, Salvatore Lentini<sup>b</sup>

\*Department of Cardiothoracic Surgery, Sahigrenska University Hospital , 413 45, Gothenburg, Sweden \*Department of Cardiac Surgery, University Hospital 'G Martino', Messina, Italy

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1141 Medline articles 186 Cochrane articles 514 CINAHL database articles 50 articles with the following cases: \*Tabata: 79 \*Byrne: 44 \*Perrotta: 40 (Bentall) \*Sun: 16 \*Svensson: 69 + 54

 Surgery of the aortic root via mini-sternotomy is SAFE, however there are not enough studies comparing minimally invasive access and conventional sternotomy

 Few reports in literature on ROOT REMODELING or REIMPLANTATION through mini-sternotomy







## **AORTIC ROOT MINI-STERNOTOMY**

Our experience at Maria Cecilia Hospital 2010 - 2014









### AORTIC ROOT REIMPLANTATION (DAVID I) via MINI-STERNOTOMY









# CONCLUSIONS

- In our experience the advantages of MIC approach include early mobilization and rehabilitation, excellent aesthetic result and lower risk of wound complications
  - Cardiopulmonary bypass, aortic crossclamp and skin-to-skin time were comparable to those operated with a standard full sternotomy approach at our department.





# CONCLUSIONS

 The total central cannulation can be easily performed:

 better venous drainage
 usual set up
 without increasing the surgical time
 avoiding groin incisions

 Our data confirms that MIC is a safe alternative for patients requiring isolated aortic valve replacement or aortic root surgery





# IN THE USUAL WAY...







