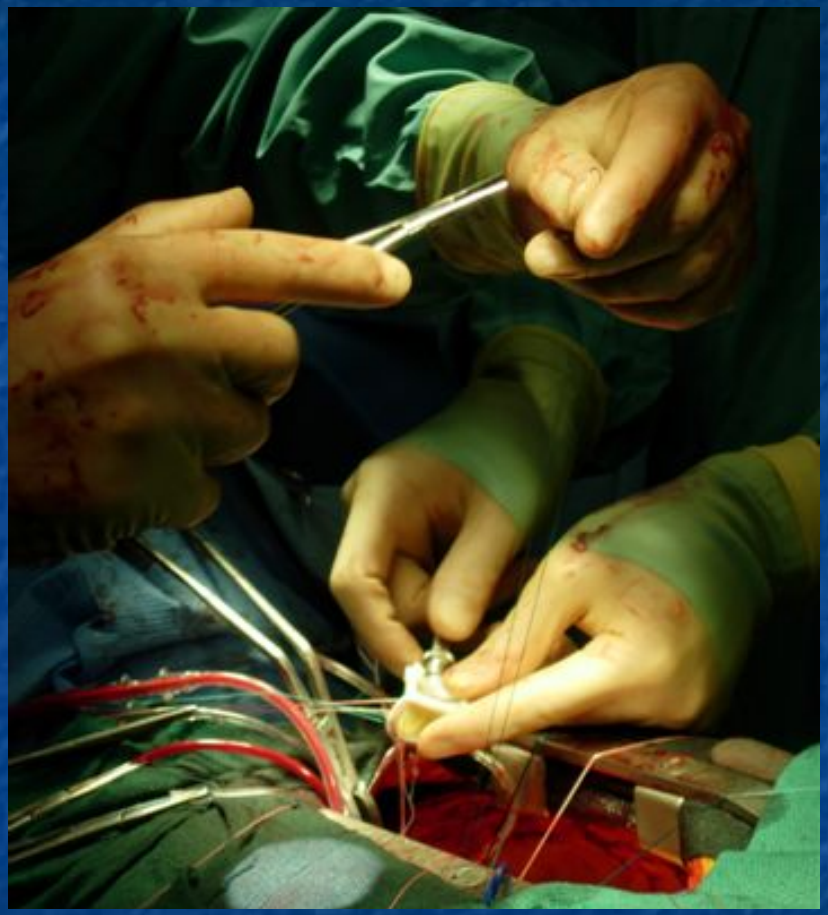
Protesi suturless. Vantaggi e risultati clinici

Dr. A. De Bellis



Protesi sutureless. Vantaggi e risultati clinici

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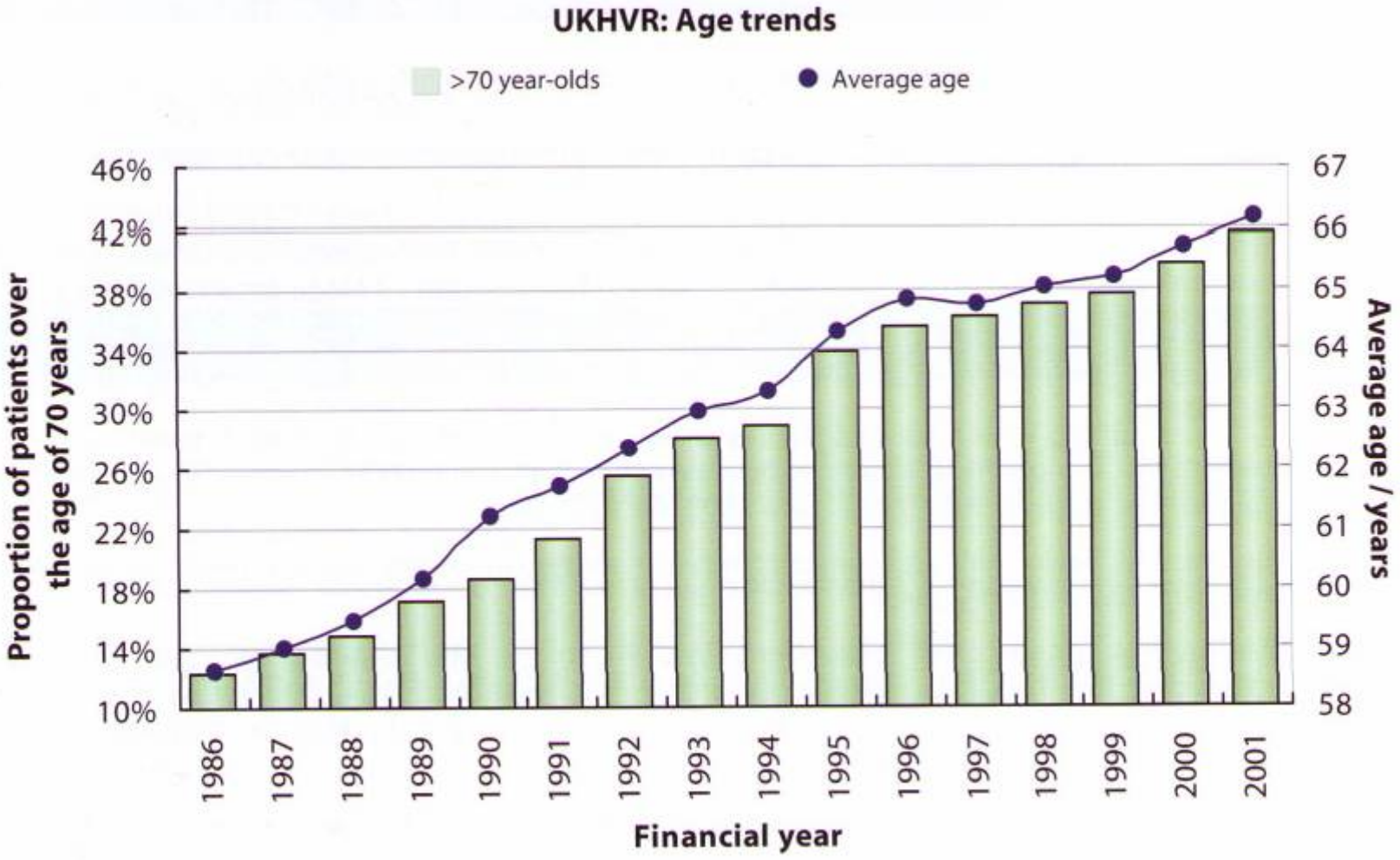
Data from 5th National Adult Cardiac Surgical Database Report



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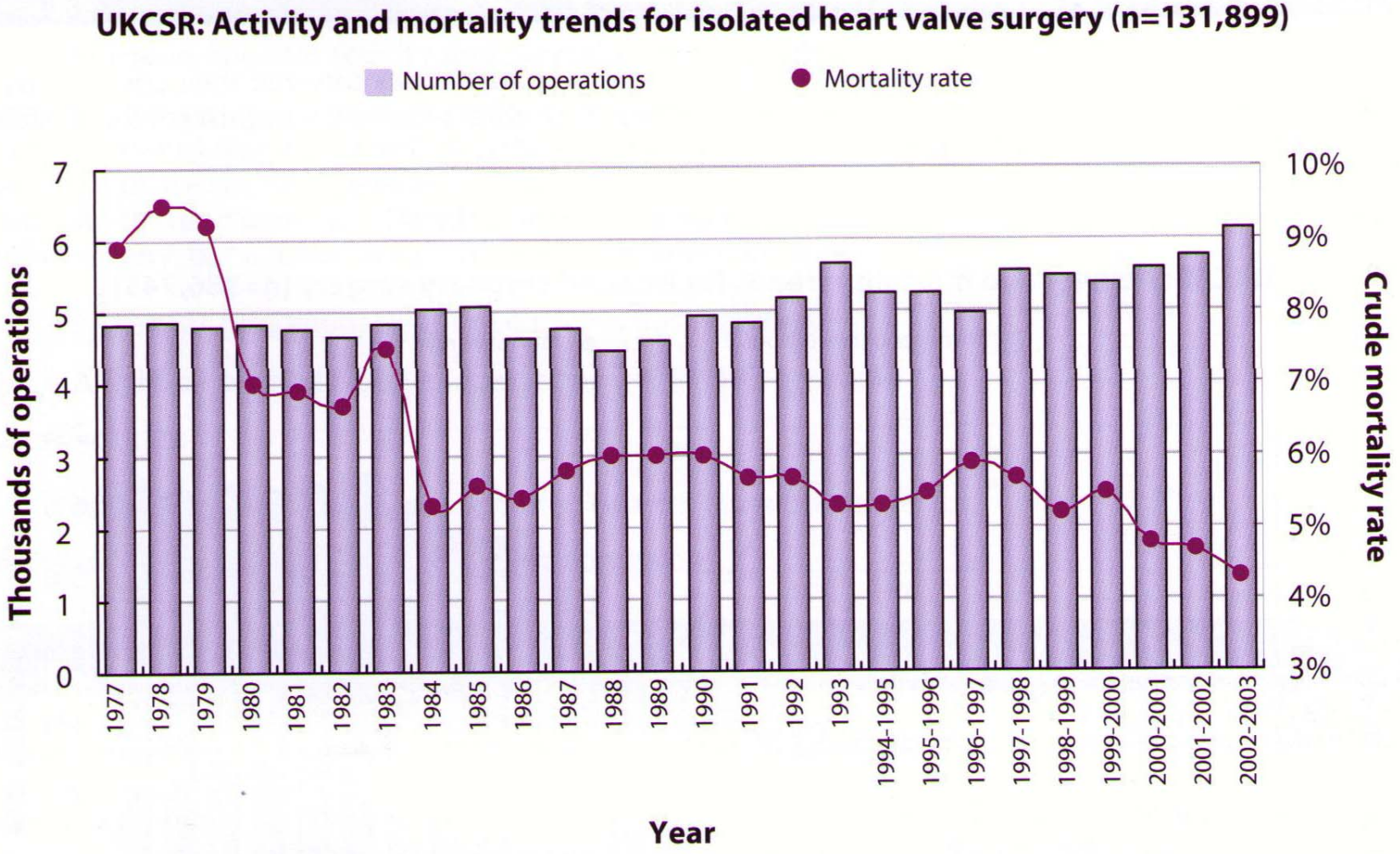

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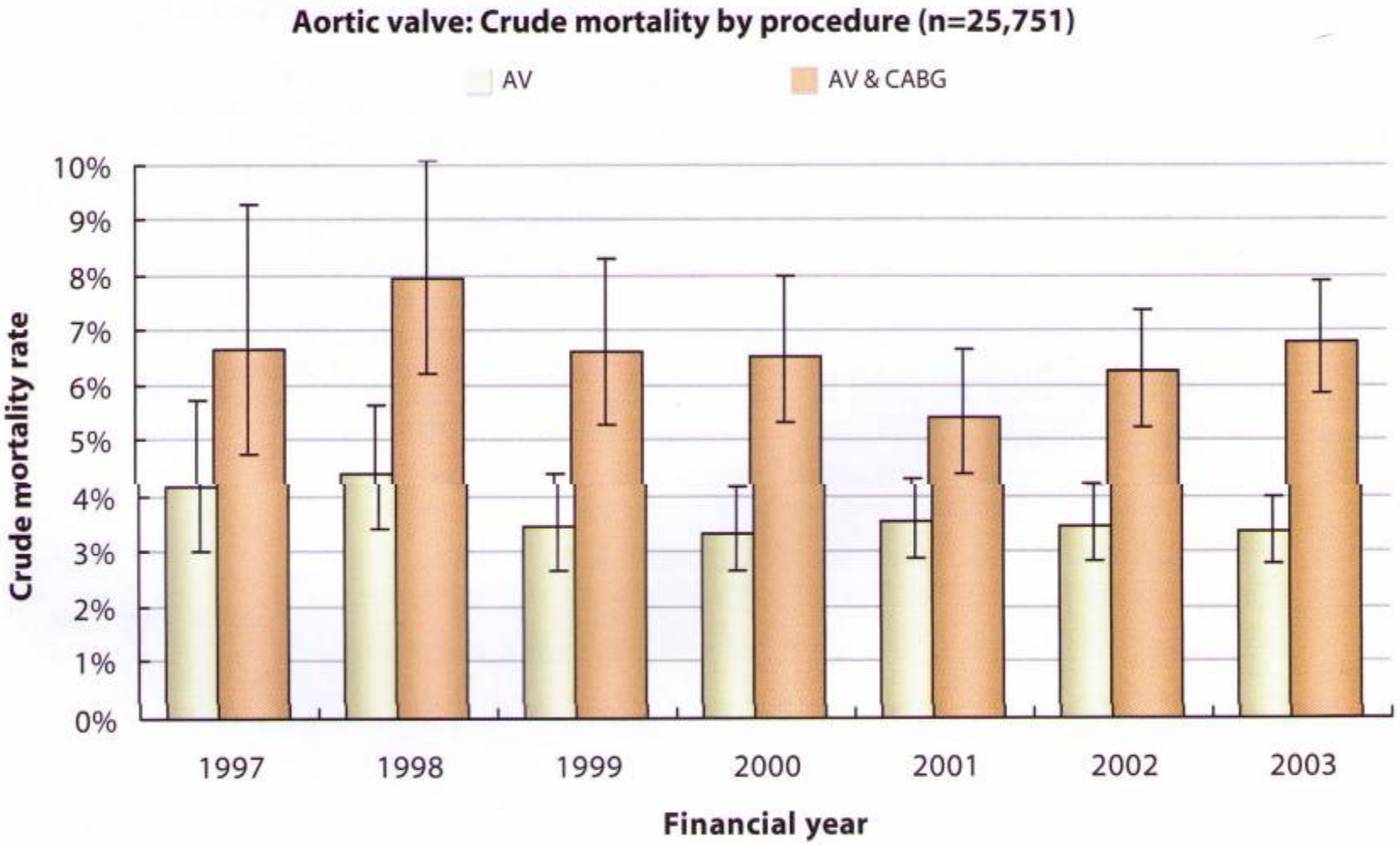
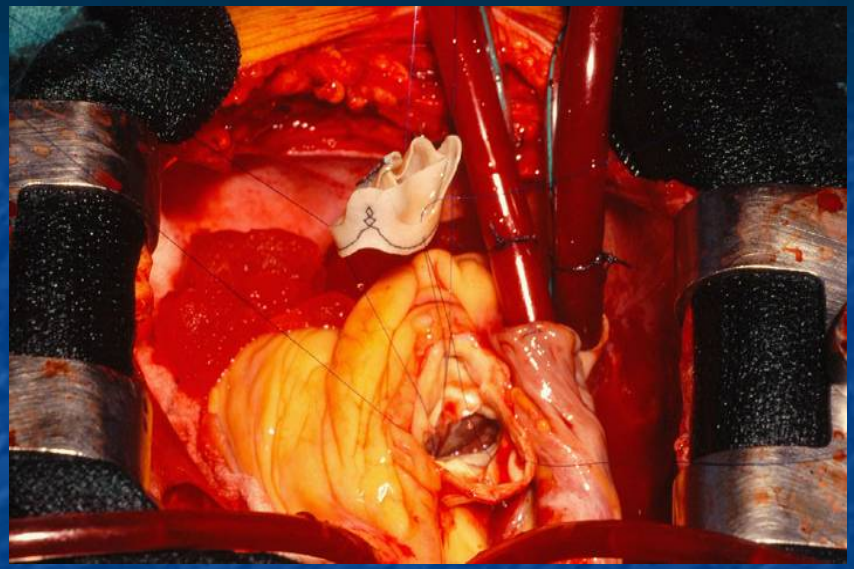
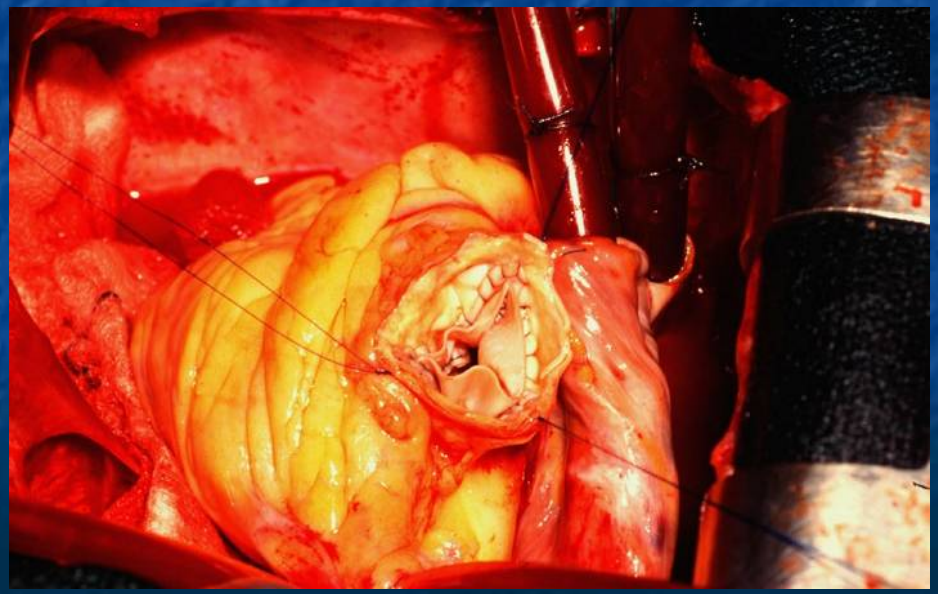
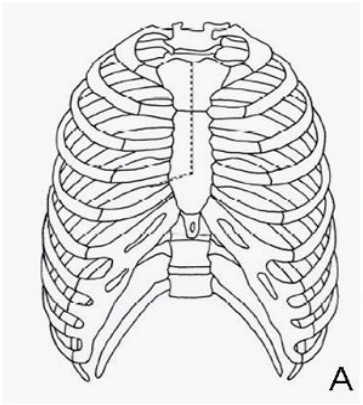


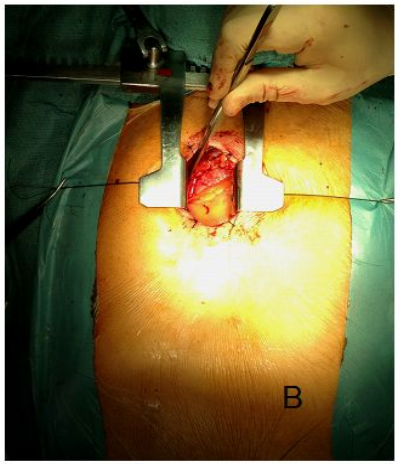
Stentless Valve



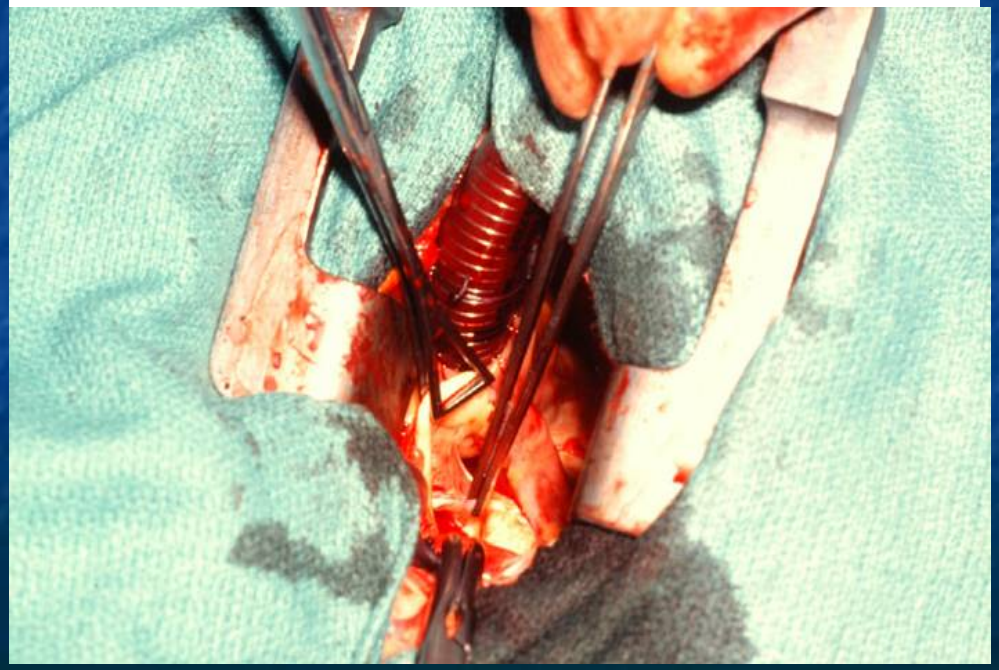


Surgical Progress





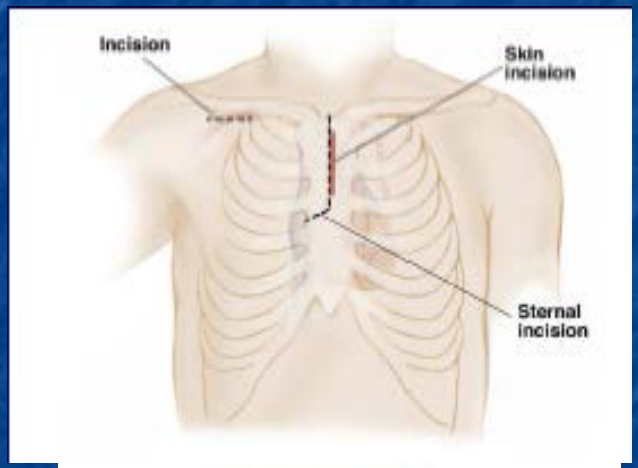
Minimal Access



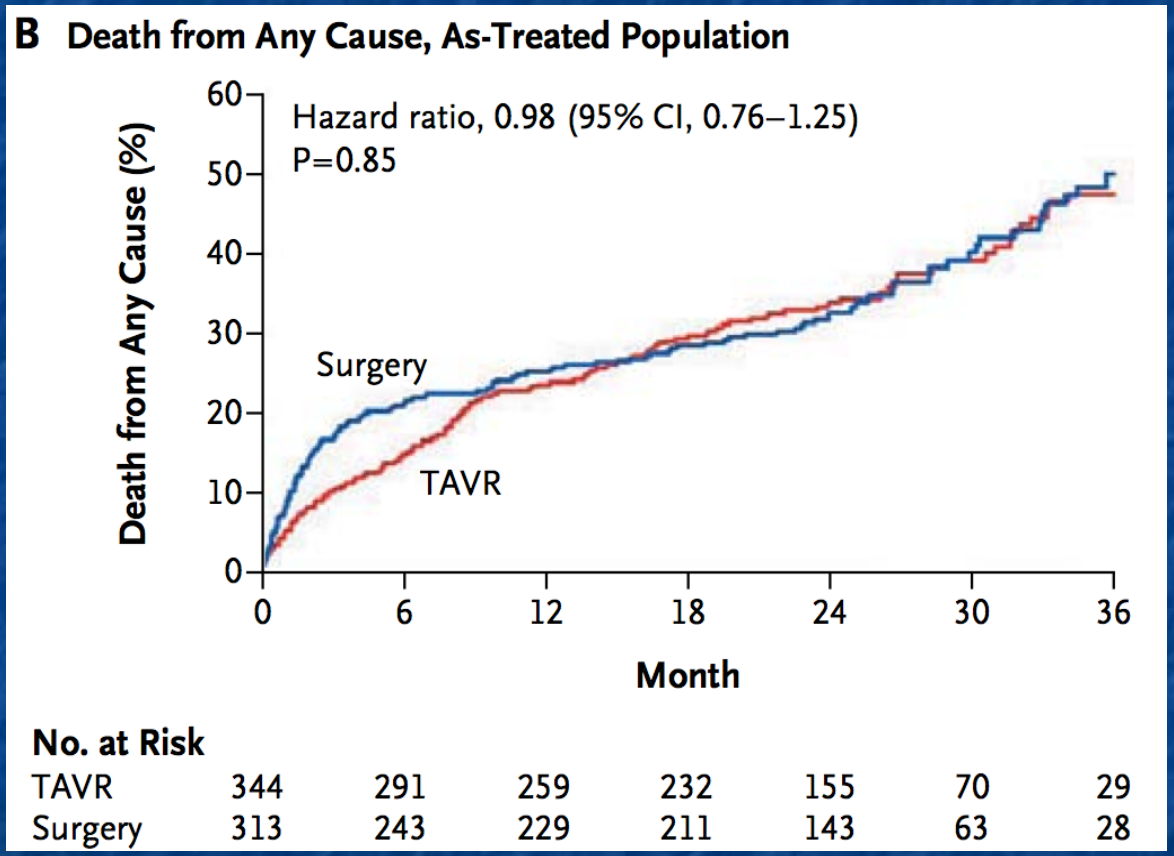
Need for less invasive approaches

TAVI

MI AVR



TAVI vs Conventional AVR Survival



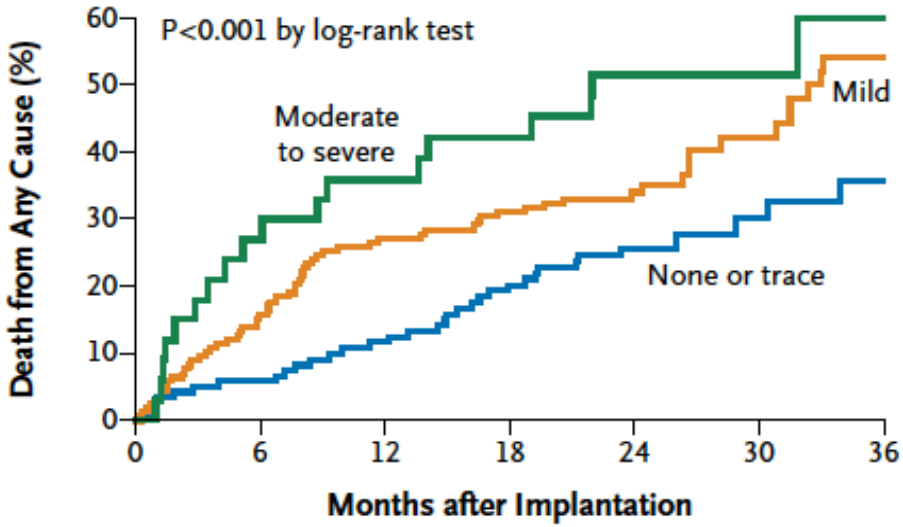
Two-Year Outcomes after Transcatheter or Surgical Aortic-Valve Replacement

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

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). Among the 143

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

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

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

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

BMJ open
accessible medical research

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

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

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]

Advantages of Sutureless Valve

- Complete excision of the diseased valve.
- Anatomical tailoring to individual patient anatomy.
- Atraumatic introduction with minimal or no crimping of the the valve leaflets allowing more predictable long term outcomes
- Valves are self anchoring (no need for sutures), self expanding for easy implantation and good visibility
- Shorter CPB
- Permits minimally invasive cardiac surgery procedures while delivering gold standard surgical outcome

Perceval S

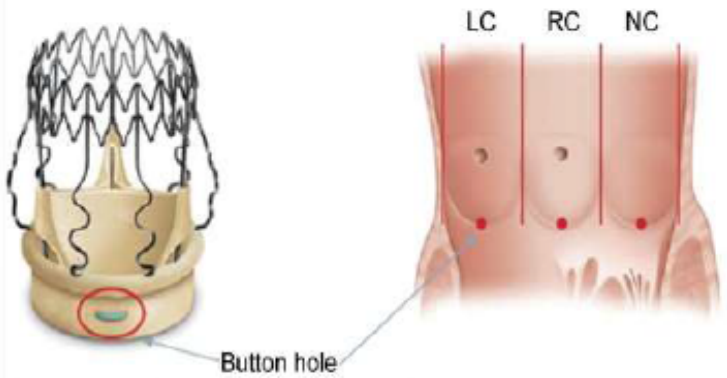


Fig 1. Valve design features: button holes. Button holes allow correct axial-rotational positioning in the native aortic root.
(LC = left coronary; NC = noncoronary; RC = right coronary.)

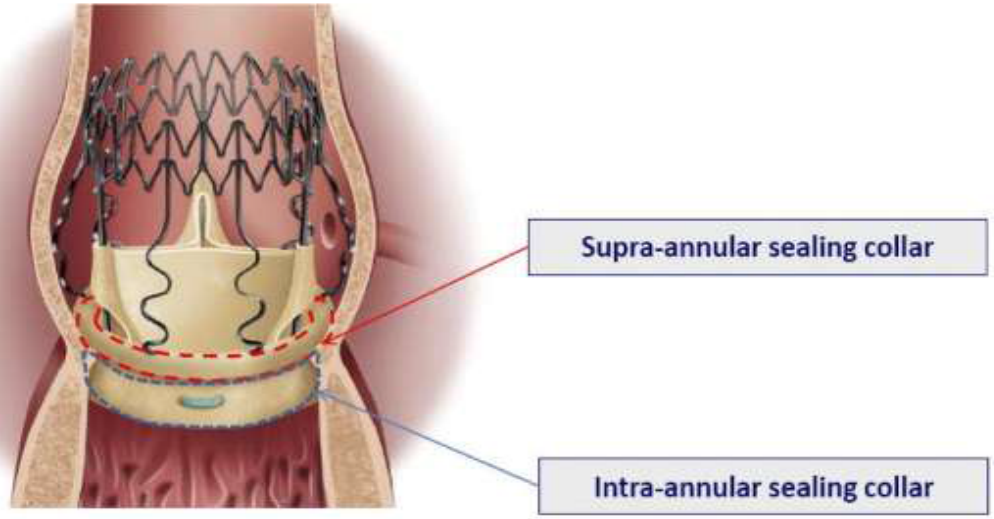


Fig 2. Valve design features dual collar design, with supraannular and intraannular sealing collar.

Perceval S - Indications

✓Subjects of age ≥ 65 years;

✓Subjects with aortic valve stenosis or steno-insufficiency

AVR patients ideal for a Perceval S:

- ✓ Small Aorta
- ✓ Small Annuli
- ✓ Calcified Aortic root
- ✓ Compromised pre-operative contractile function
- ✓ Higher-risk patients requiring concomitant procedure (CABG)
- ✓ Respiratory disorders (COPD)
- ✓ Patients previously implanted with "stentless" prosthesis

Major Exclusion Criteria

- Pure aortic regurgitation
- Congenital bicuspid aortic valve
- Subjects with aortic root enlargement

INTUITY VALVE SYSTEM

Model 8300A

Model 8300A
Deployed

EDWARDS INTUITY
Valve System

Aortic Valve

- Sterilized in glutaraldehyde
- Valve is inverted in the jar to facilitate attachment of the delivery system

Delivery System

- Ethylene oxide (ETO) sterilized
- Components secured on a plastic card
- Single barrier peel pouch

Inflation Device

- Ethylene oxide (ETO) sterilized
- Secured in a tray
- Single barrier peel

Indications and Contraindications

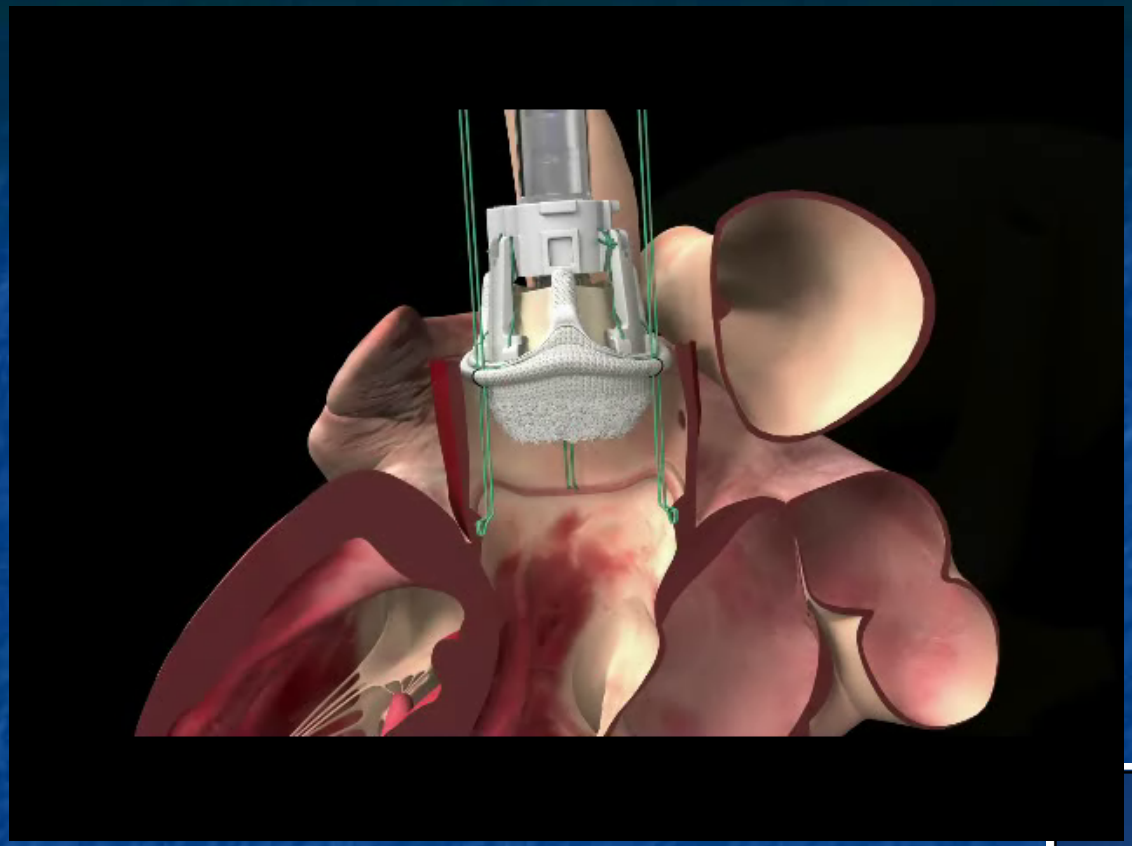
INDICATIONS

- For patients whose aortic valve disease is sufficiently advanced to warrant replacement of their native valve
- Also intended for re-do patients in which the previously implanted prosthesis is excised and replaced with the EDWARDS INTUITY valve

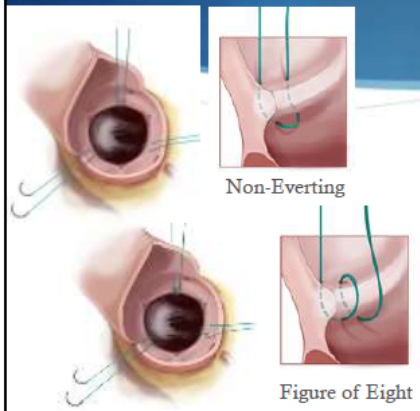
CONTRAINDICATIONS

- Pure aortic insufficiency
- Aneurysms of the aortic root or ascending aorta
- History of active endocarditis within 3 months of scheduled surgery

Warning: The safety and effectiveness of the EDWARDS INTUITY valve has not been established for patients with a congenital bicuspid or unicuspid aortic valve, because it has not been studied in these populations



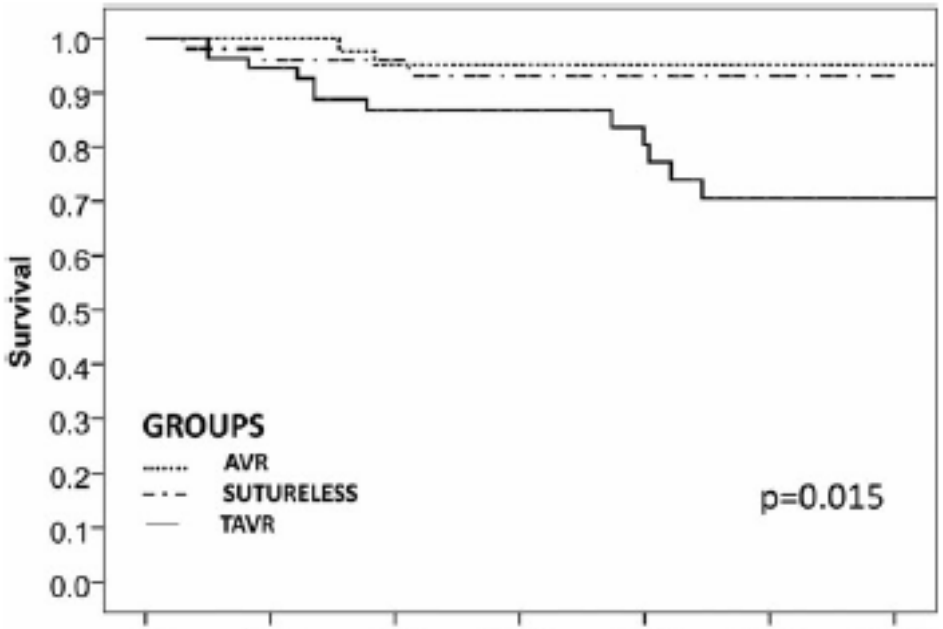
Guiding Suture Placement in the Annulus



- Conventional suture techniques, such as non-everting mattress, figure of eight or simple can be used with this valve
- Three annular sutures equally spaced and placed in the middle of each sinus to guide the valve onto the annulus
- Non-pledgetted, braided sutures are recommended

Treating the patients in the 'grey-zone' with aortic valve disease: a comparison among conventional surgery, sutureless valves and transcatheter aortic valve replacement

Interactive CardioVascular and Thoracic Surgery 20 (2015) 90–95
doi:10.1093/icvts/ivu340 Advance Access publication 15 October 2014



Patients at risk

AVR	55	43	34	28	24	20	14
SUTURELESS	53	45	31	29	12	3	2
TAVR	55	48	39	32	24	15	5

Figure 3: Composite end-point of survival free from MACCEs (defined as cardiac-related mortality, myocardial infarction, cerebrovascular accidents and major haemorrhagic events) and prosthesis dysfunction (aortic regurgitation ≥2).

CONCLUSIONS: This preliminary study suggests that the use of TAVR in patients with an intermediate- to high-risk profile is associated with a higher rate of perioperative complications and decreased survival at the 24-month follow-up compared with the use of conventional surgery or sutureless valves.

J Thorac Cardiovasc Surg. 2014 Sep;148(3):865-71; discussion 871. doi: 10.1016/j.jtcvs.2014.03.052. Epub 2014 Apr 4.

Early and intermediate outcome after aortic valve replacement with a sutureless bioprosthesis: Results of a multicenter study.

METHODS:

This is a retrospective analysis of 314 patients (mean age, 77.9 ± 5.0 years, mean European System for Cardiac Operative Risk Evaluation II, 9.0% ± 7.6%) who underwent aortic valve replacement with the Perceval S valve with (94 patients) or without (220 patients) concomitant coronary artery bypass surgery at 5 European centers.

CONCLUSIONS:

The sutureless Perceval S valve is associated with excellent early survival in high-risk patients, particularly among those undergoing an isolated procedure. Further studies are needed to prove the durability of this bioprosthesis.

Left ventricular mass regression after sutureless implantation of the Perceval S aortic valve bioprosthesis: preliminary results

Interactive CardioVascular and Thoracic Surgery 18 (2014) 38–42
doi:10.1093/icvts/ivt362 Advance Access publication 8 October 2013

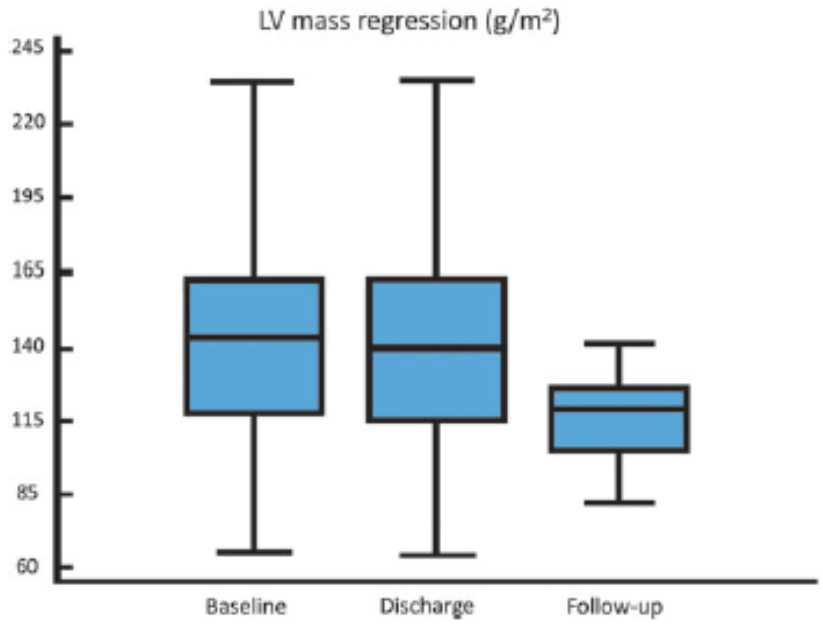


Figure 1: Changes in left ventricular (LV) mass between baseline, discharge and follow-up.

Table 4: Aortic valve echocardiographic data and clinical status

Variables	Baseline	Discharge	Follow-up
Mean aortic gradient (mmHg)	49.5 ± 15.8	11.6 ± 5.1	8.3 ± 4.4
Paravalvular leakage		0	0
Intravalvular leakage		2	1
NYHA class (1–4)	2.9 ± 0.5		1.2 ± 0.5

Values are means ± SD or numbers.
NYHA: New York Heart Association.

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

Conclusions: Implantation of the EDWARDS INTUITY Valve System is feasible, safe, and efficacious for aortic valve replacement. Aortic crossclamp and cardiopulmonary bypass times were reduced compared with those for conventional aortic valve replacement. Early hemodynamic performance was excellent and remained so up to 1 year. (J Thorac Cardiovasc Surg 2013;145:110-6)

TABLE 2. Intraoperative data

Parameter	n (%) or mean ± SD
Valve size (mm) (n = 146)	
19	1 (0.7 %)
21	50 (34.2 %)
23	52 (35.6 %)
25	35 (24.0 %)
27	8 (5.5 %)
Procedures (n = 146)	
AVR only	86 (58.9 %)
AVR + CABG	36 (24.7 %)
AVR + other	24 (16.4 %)
Surgical approach (n = 146)	
Full sternotomy	102 (69.9 %)
Minimally invasive approach	44 (30.1 %)
Upper hemisternotomy	43 (29.5 %)
Right anterior minithoracotomy	1 (0.7 %)
Deployment time (min) (n = 133)*	9.7 ± 4.3
Valve implant time (min) (n = 145)†	11.0 ± 6.6
Crossclamp time (min) (n = 134)‡	46.6 ±16.4
AVR only (n = 80)	41.1 ± 10.6
AVR + CABG (n = 32)	60.0 ± 19.0
AVR + other (n = 22)	47.0 ± 19.2
CPB time (min) (n = 134)‡	75.1 ± 26.4
AVR only (n = 80)	66.3 ± 18.7
AVR + CABG (n = 32)	95.6 ± 30.4
AVR + other (n = 22)	77.2 ± 28.1

TABLE 3. Early and late complications

Parameter	Early (≤30 d) (n = 146) N (%)	Late (>30 d) (late patient-y = 107.28) N (%)
Mortality		
All cause	3 (2.1%)	8 (7.5%)
Valve related	2 (1.4%)	2 (1.9%)
Thromboembolism	4 (2.7%)	2 (1.9%)
Reoperation for bleeding	1 (0.7%)	0 (0.0%)
Paravalvular leak (>1+)	2 (1.4%)	1 (0.9%)
Explant	2 (1.4%)	2 (1.9%)
Endocarditis	0 (0.0%)	0 (0.0%)
Hemolysis	0 (0.0%)	0 (0.0%)
Structural valve deterioration	0 (0.0%)	0 (0.0%)

Three-year hemodynamic performance, left ventricular mass regression, and prosthetic-patient mismatch after rapid deployment aortic valve replacement in 287 patients

Conclusions

In a large series of elderly patients with symptomatic severe aortic stenosis, rapid deployment aortic valve replacement using a subannular balloon-expandable stent frame demonstrated excellent hemodynamic performance and significant left ventricular mass regression. With continued follow-up, future studies will establish whether these favorable structural changes correlate with improvement in long-term survival and functional status.

A Randomized Multicenter Trial of Minimally Invasive Rapid Deployment Versus Conventional Full Sternotomy Aortic Valve Replacement

Table 2. Procedural Outcomes

Characteristic	MIS-RDAVR (n = 46)	FS-AVR (n = 48)
Cross-clamp time	41.3 ± 20.3 (35.0; 29.0–45.0)	54.0 ± 20.3 (47.5; 38.5–65.5)
Cardiopulmonary bypass time	68.8 ± 29.0 (58.5; 51.0–71.0)	74.4 ± 28.4 (69.0; 51.5–86.0)
Operative time	141.9 ± 46.1 (130.0; 110.0–156.0)	146.4 ± 48.4 (145.5; 108.5–166.0)
Implanted valve size, mm	22.9 ± 2.1 (23; 21–25)	23.0 ± 2.1 (23; 21–25)

Table 3. Early (≤30 Days) Clinical Outcomes

Outcome	MIS-RDAVR (n = 46)	FS-AVR (n = 48)
Mortality	4.3% (2)	2.1% (1)
Reoperation	2.2% (1)	2.1% (1)
Major bleeding	6.5% (3)	8.3% (4)
New pacemaker	4.3% (2)	0.0% (0)
Cerebrovascular accident	4.3% (2)	2.1% (1)
Sternal wound infection	4.3% (2)	6.3% (3)
Respiratory failure	4.3% (2)	2.1% (1)
Renal failure	4.3% (2)	0.0% (0)
Endocarditis	0.0% (0)	0.0% (0)
Myocardial infarction	0.0% (0)	2.1% (1)
Paravalvular leak[a]		
0 (none)	85.3% (29)	73.7% (28)
1+ (trace)	11.8% (4)	23.7% (9)
2+ (mild)	2.9% (1)	2.6% (1)
>3+ (moderate/severe)	0.0% (0)	0.0% (0)

Conclusions. RDAVR by the MIS approach is associated with significantly reduced myocardial ischemic time and better valvular hemodynamic function than FS-AVR with a conventional stented bioprosthesis. Rapid deployment valves may facilitate the performance of MIS-AVR.

Conclusioni

Sutureless aortic valve replacement is safe and has excellent early and mid outcome.

Perfectly suitable for small aortic roots and poor ejection fraction patients

Reduces ischemic and pump time

Long term outcome is still awaited