Molinette Hospital experience with….

TRANSCATHETER AORTIC-VALVE IMPLANTATION

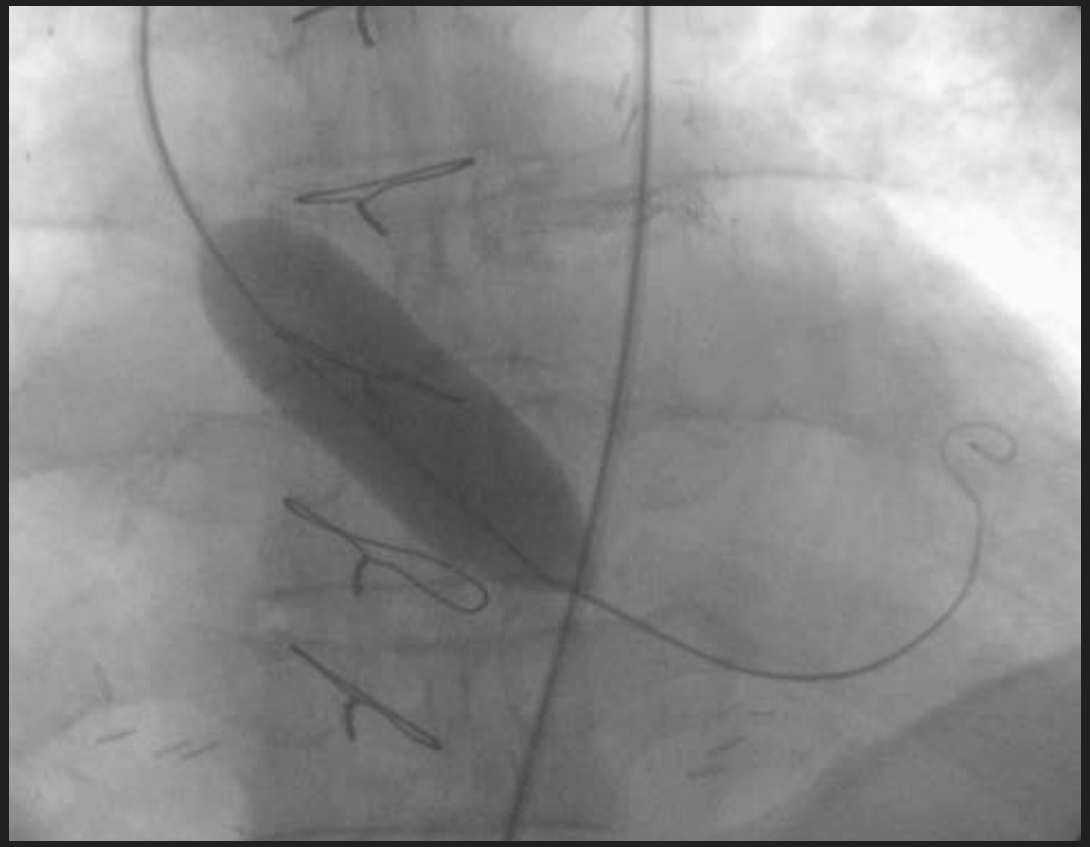
Turin
25, October

Maurizio D'Amico

Dipartimento cardiovascolare e toracico

Balloon Valvuloplasty

The History



1985… the first ballon aortic valvuloplasty …

Percutaneous transluminal valvuloplasty of acquired aortic stenosis in elderly patients: An alternative to valve replacement?

***Cribier** A, Savin T, Saoudi N, Rocha P, Berland J, Letac B*

Lancet 1986;1:63-67

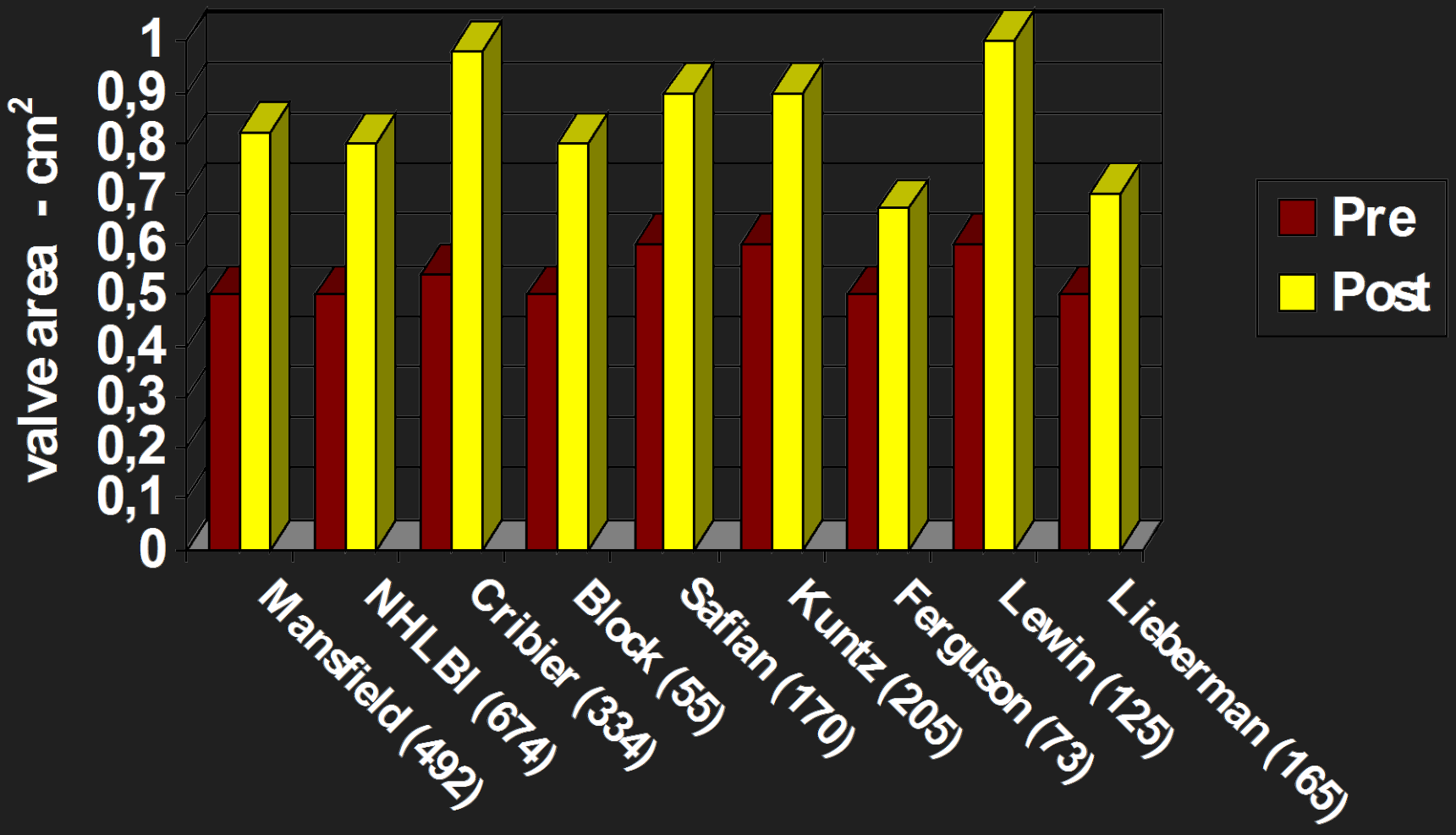
Balloon Aortic Valvuloplasty

Major Series

- ✓ **Mansfield Scientific Registry, n = 492**
- ✓ **NHLBI (National Heart, lung and blood Institution) Registry, n = 674**
- ✓ **Cribier (French Registry), n = 406**
- ✓ Block , n = 375
- ✓ Safian , n = 170
- ✓ Lieberman , n = 165
- ✓ Lewin , n = 125
- ✓ Ferguson , n = 73

Balloon Aortic Valvuloplasty

HEMODINAMIC RESULTS



Balloon Aortic Valvuloplasty

Acute Hemodynamic Results

674 pts in NHLBI Registry

44% M; 56%F; 78 ±9 yrs	Before	After BAV	p
Valve Gradient, mmHg			
Mean	55 ±21	29 ±13	<0.0001
Peak to peak	65 ±28	31 ±18	
Valve Area, cm^2	0.5 ±0.2	0.8 ±0.3	<0.0001
Cardiac output, L/min	4.0 ±1.2	4.1 ±1.3	<0.0001
Aortic Pressure, mmHg	87 ±16	90 ±17	<0.0001
LV systolic Pressure, mmHg	196 ±39	172 ±32	<0.0001
LVEDP, mmHg	22 ±9	19 ±9	<0.0001
PA Pressure, mmHg	31 ±13	30 ±12	<0.0001

Circ 1991;84:2383-2397

Balloon Aortic Valvuloplasty

Acute Hemodynamic Results

Valve Area

AVA increased 0.5 ±0.2 to 0.8 ±0.3 cm^2

Range 0.1 – 1.4 to 0.1 – 3.4 cm^2

- 77% Δ AVA < 0.4 cm^2
- 13% Δ AVA 0 cm^2
- AVA_F ≥ 1cm^2 in only 29%

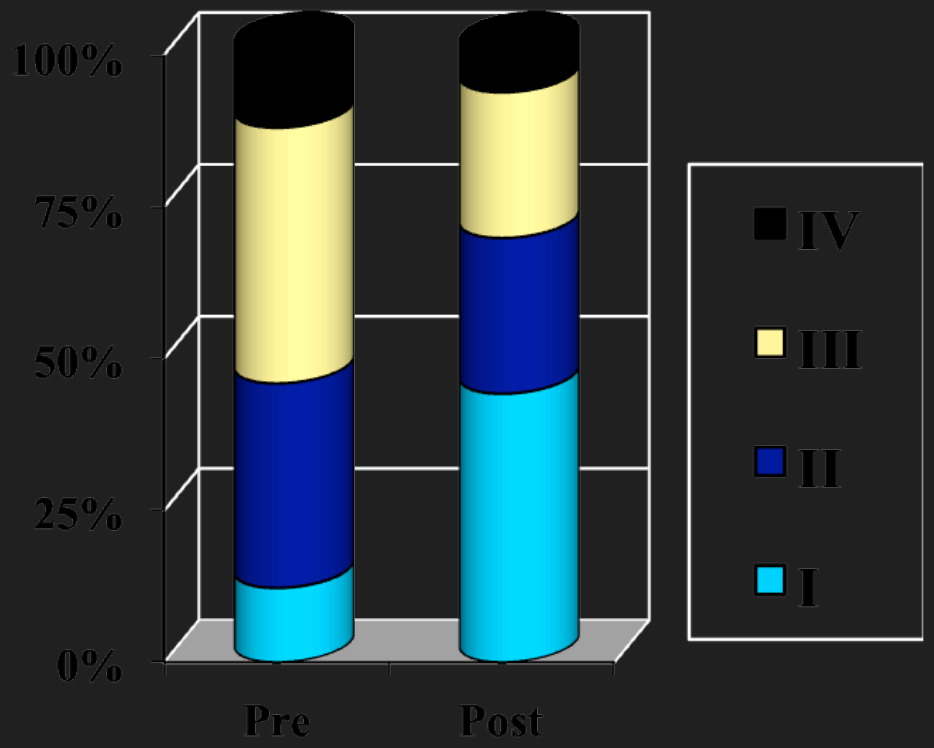
"Start with AS and end with AS"

NHLBI. n = 674

Circ 1991;84:2383-2397

Balloon Aortic Valvuloplasty

30 Day NYHA



NYHA Functional Class

(364 improved)

484 Survivors from NHLBI Registry

Balloon Aortic Valvuloplasty

Clinical Follow-up

Mansfield Registry Data

	Pre (%)	6m f/u (%)	p
CHF	**54**	**49**	**ns**
Fatigue	**59**	**61**	**ns**
Dyspnoea	**87**	**71**	**ns**
NYHA III/IV	**71**	**57**	**<0.05**
Angina	**53**	**33**	**<0.05**
Syncope	**23**	**12**	**<0.05**

n = 95

Bashore JACC 1991:1188

BAV FAILURE

JACC Vol. 26, No. 6
November 15, 1995:1522–8

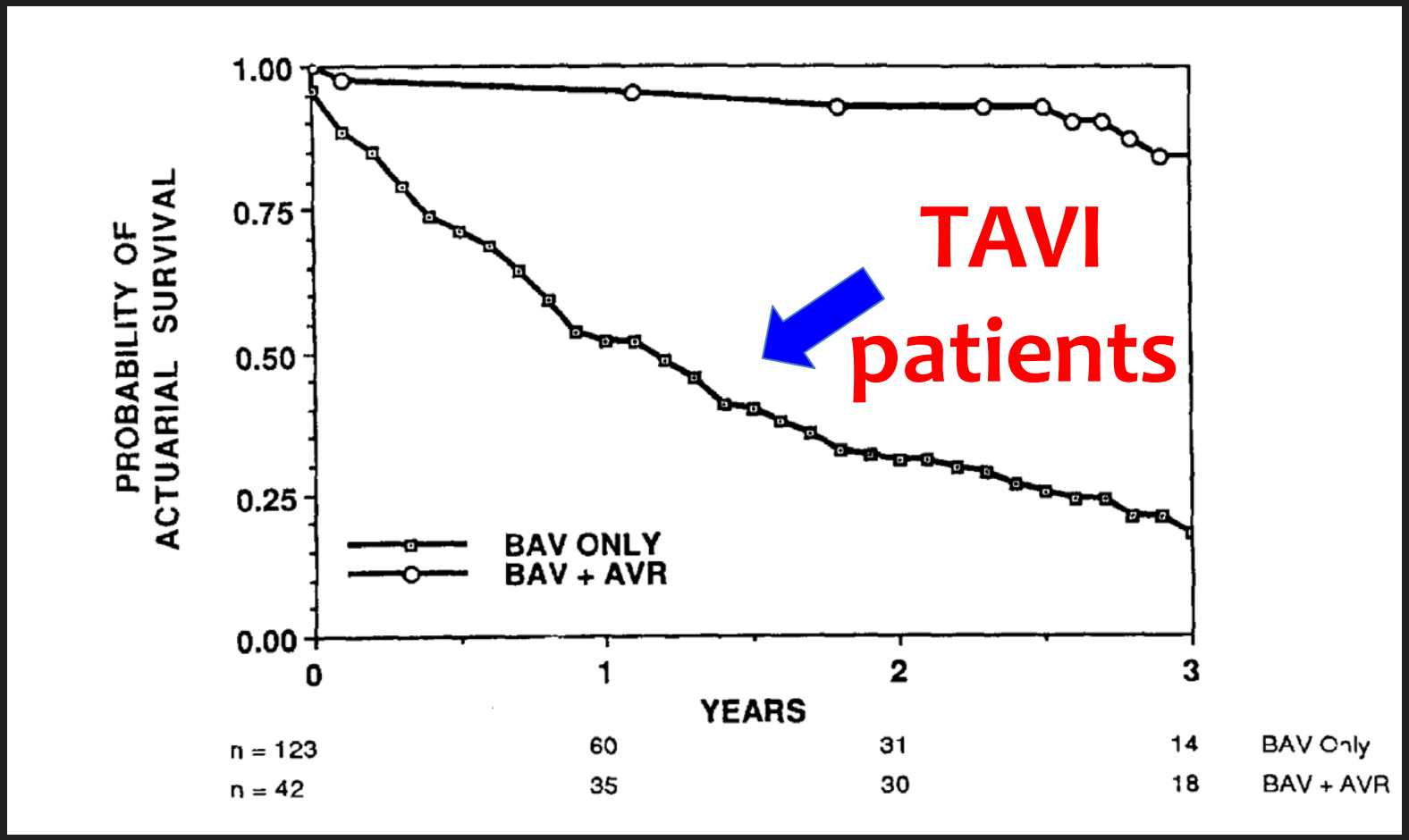
Balloon Aortic Valvuloplasty in Adults: Failure of Procedure to Improve Long-Term Survival

ERIC B. LIEBERMAN, MD, FACC, THOMAS M. BASHORE, MD, FACC,
JAMES B. HERMILLER, MD, FACC, JOHN S. WILSON, MD, KAREN S. PIEPER, MS,
GORDON P. KEELER, MS, CYNTHIA H. PIERCE, RN, KATHERINE B. KISSLO, RDMS,
J. KEVIN HARRISON, MD, CHARLES J. DAVIDSON, MD, FACC

Durham, North Carolina

Figure 4. Actuarial survival from the date of balloon aortic valvuloplasty in patients who subsequently underwent aortic valve replacement (BAV + AVR) and those treated by balloon aortic valvuloplasty alone (BAV only).

BAV FAILURE



JACC Vol. 26, No. 6
November 15, 1995:1522–8

Aortic Stenosis

Recommendations for Aortic Balloon Valvoplasty in Adults With Aortic Stenosis

Indication	Class
A bridge to surgery in hemodynamically unstable patients who are at high risk for AVR	IIa
Palliation in patients with serious comorbid conditions	IIb
Patients who require urgent non cardiac surgery	IIb
As an alternative to AVR	III

Bonow et al. 1998 ACC/AHA Task Force

Balloon Aortic Valvuloplasty

- Because of a prohibitively high restenosis rate, this procedure fell into disfavor soon after its introduction in 1985
- Although the procedure was generally abandoned after 1990, some centers have continued to perform it on a regular basis for true “no option” patients

Molinette Hospital experience with….

FIRST BAV EXPERIENCE IN OUR CENTER

1987-1993

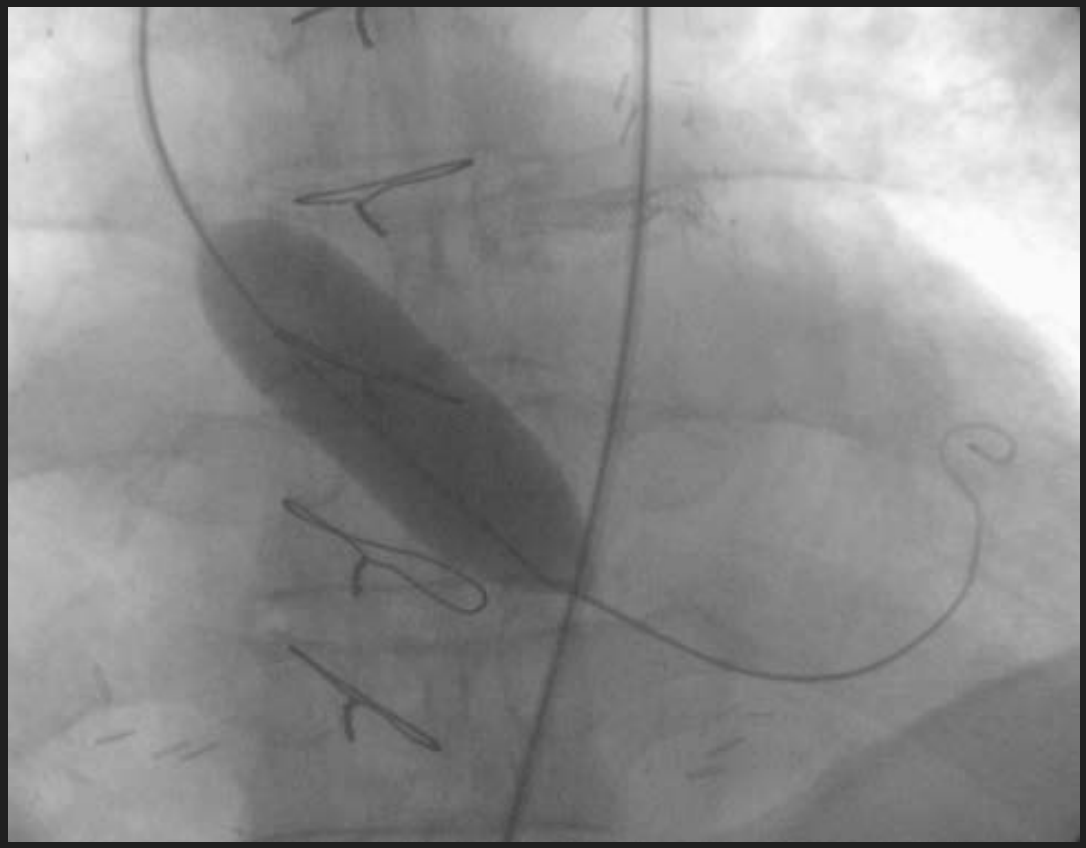
46 Balloon aortic valvuloplasty in 31 pts (Max 4 per pt)

Dr. F ORZAN

The introduction of transcatheter aortic valve implantation (TAVI) has led to a revival balloon aortic valvuloplasty (BAV) as treatment of patients with severe aortic stenosis

Balloon Aortic Valvuloplasty

DECEMBER 2006
BAV PROCEDURE



Molinette Hospital experience with....

Transcatheter aortic-valve implantation

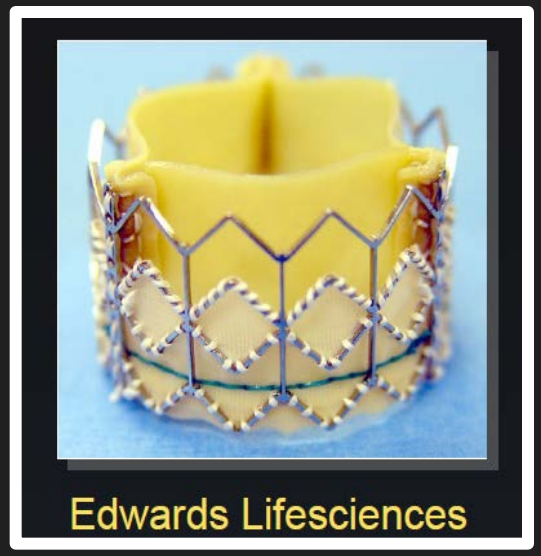
Our pathway to TAVI

Molinette Hospital experience with….

CORE VALVE

First TF: may-2008

First TS: december-2010



EDWARDS

First TA: february-2009

First TF: march-2009

European Heart Journal (2008) **29**, 1463–1470
doi:10.1093/eurheartj/ehn183

SPECIAL ARTICLE

Transcatheter valve implantation for patients with aortic stenosis: a position statement from the European Association of Cardio-Thoracic Surgery (EACTS) and the European Society of Cardiology (ESC), in collaboration with the European Association of Percutaneous Cardiovascular Interventions (EAPCI)

Indicazioni all'impianto di protesi aortiche trans-catetere (Percutanee e Transapicali)

D.G.R. n° 16 – 11109 del 30/03/2009

1. Stenosi aortica valvolare severa
2. Elevato/proibitivo rischio chirurgico: Euroscore additivo > 10
3. Parere multidisciplinare di non operabilità
4. Parere combinato cardiologo interventista, cardiochirurgo, anestesista rianimatore
5. Presenza di unità operativa di cardiochirurgia
6. Parere del paziente (l'esplicita richiesta del pz non può essere considerata un'indicazione al trattamento)
7. Consenso informato scritto

Indications for transcatheter aortic valve implantation

	Class	Level
TAVI should only be undertaken with a multidisciplinary "heart team" including cardiologists and cardiac surgeons and other specialists if necessary.	I	C
TAVI should only be performed in hospitals with cardiac surgery on-site.	I	C
TAVI is indicated in patients with severe symptomatic AS who are not suitable for AVR as assessed by a " heart team" and who are likely to gain improvement in their quality of life and to have a life expectancy of more than 1 year after consideration of their comorbidities.	I	B
TAVI should be considered in high risk patients with severe symptomatic AS who may still be suitable for surgery, but in whom TAVI is favoured by a "heart team" based on the individual risk profile and anatomic suitability.	IIa	B

« At the present stage, TAVI should not be performed in patients at intermediate risk for surgery and trials are required in this population. »

European Heart Journal 2012 - doi:10.1093/eurheartj/ehs109 & European Journal of Cardio-Thoracic Surgery 2012 - doi:10.1093/ejcts/ezs455).

Contraindications for transcatheteter aortic valve implantation

Absolute contraindications

Absence of a "heart team" and no cardiac surgery on the site.
Appropriateness of TAVI, as an alternative to AVR, not confirmed by a "heart team".

Clinical

- Estimated life expectancy < 1 year.
- Improvement of quality of life by TAVI unlikely because of comorbidities.
- Severe primary associated disease of other valves with major contribution to the patient's symptoms that can be treated only by surgery.

Anatomical

- Inadequate annulus size (< 18 mm, > 29 mm).
- Thrombus in the left ventricle.
- Active endocarditis.
- Elevated risk of coronary ostium obstruction (asymmetric valve calcification, short distance between annulus and coronary ostium, small aortic sinuses).
- Plaques with mobile thrombi in the ascending aorta, or arch.
- For transfemoral/subclavian approach: inadequate vascular access (vessel size, calcification, tortuosity).

Relative contraindications

- Bicuspid or non-calcified valves.
- Untreated coronary artery disease requiring revascularization.
- Haemodynamic instability.
- LVEF < 20%.
- For transapical approach: severe pulmonary disease, LV apex not accessible.

European Heart Journal 2012 - doi:10.1093/eurheartj/ehs109 &
European Journal of Cardio-Thoracic Surgery 2012 -
doi:10.1093/ejcts/ezs455).

Canadian Journal of Cardiology 28 (2012) 520–528

Society Position Statement

Transcatheter Aortic Valve Implantation: A Canadian Cardiovascular Society Position Statement

John Webb, MD, FRCPC,[a] Josep Rodés-Cabau, MD, FRCPC,[b] Stephen Fremes, MD, FRCSC,[c] Philippe Pibarot, DVM, PhD,[b] Marc Ruel, MD, FRCSC,[d] Reda Ibrahim, MD, FRCPC,[e] Robert Welsh, MD, FRCPC,[f] Christopher Feindel, MD, FRCSC,[g] and Samuel Lichtenstein, MD, FRCSC[a]

[a] *St Paul's Hospital, University of British Columbia, Vancouver, British Columbia, Canada*

[b] *Quebec Heart and Lung Institute, Québec City, Québec, Canada*

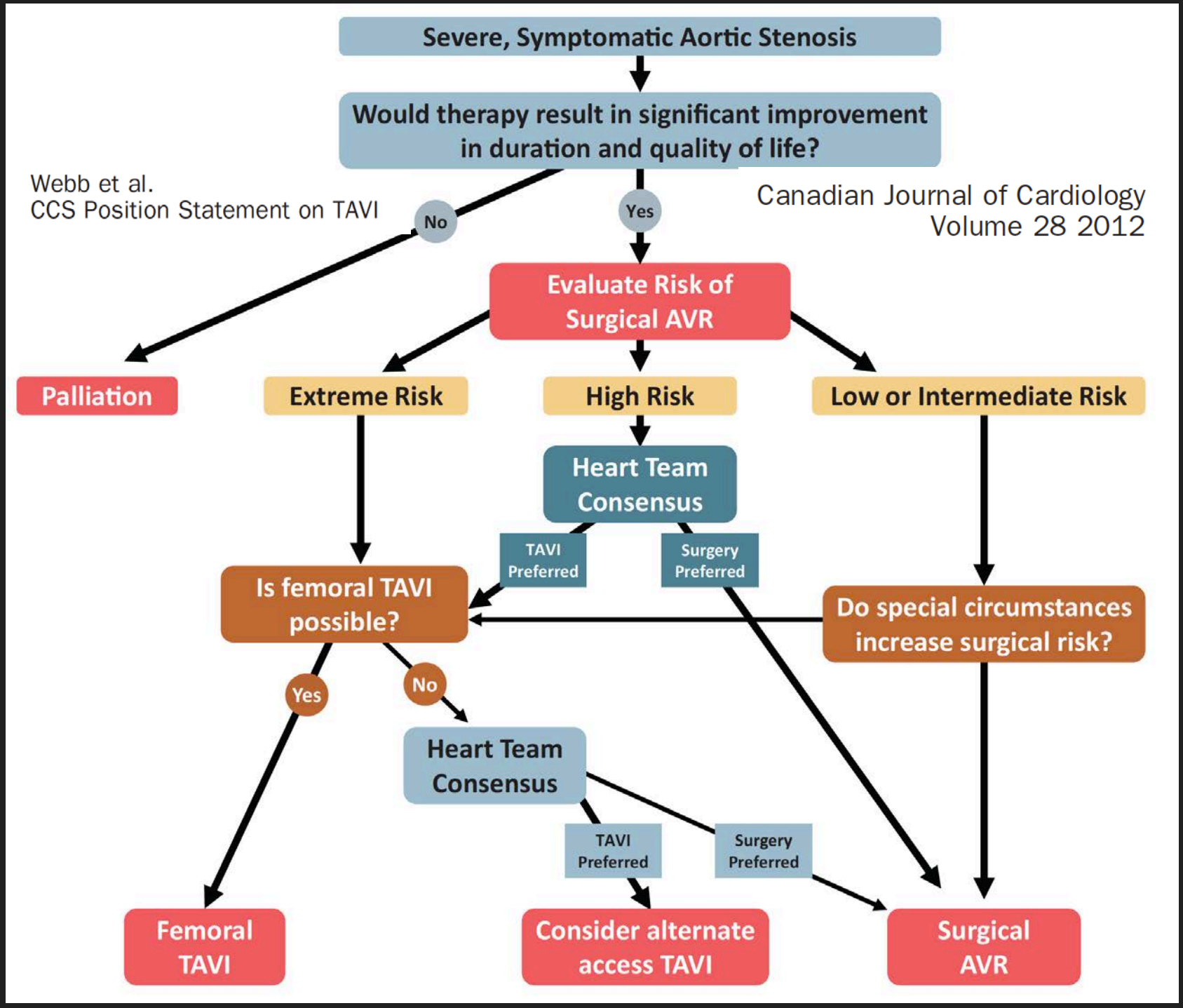
[c] *SunnyBrook Hospital, Toronto, Ontario, Canada*

[d] *University of Ottawa Heart Institute, Ottawa, Ontario, Canada*

[e] *Montreal Heart Institute, Montreal, Québec, Canada*

[f] *University of Alberta, Edmonton, Alberta, Canada*

[g] *Toronto General Hospital, Toronto, Ontario, Canada*


Severe, Symptomatic Aortic Stenosis
Would therapy result in significant improvement in duration and quality of life?
Webb et al.
CCS Position Statement on TAVI
Canadian Journal of Cardiology
Volume 28 2012
No
Yes
Evaluate Risk of Surgical AVR
Palliation
Extreme Risk
High Risk
Low or Intermediate Risk
Heart Team Consensus
TAVI Preferred
Surgery Preferred
Is femoral TAVI possible?
Do special circumstances increase surgical risk?
Yes
No
Heart Team Consensus
TAVI Preferred
Surgery Preferred
Femoral TAVI
Consider alternate access TAVI
Surgical AVR

RECOMMENDATION

For TAVI in patients with AS: PROHIBITIVE RISK

1. Transfemoral TAVI is recommended if:
a. The risk of open heart surgery is prohibitive; and
b. A significant improvement in duration or quality of life is likely; and
c. Life expectancy with treatment is likely to exceed 1 to 2 years
(Strong Recommendation, High-Quality Evidence).

Canadian Journal of Cardiology
Volume 28 2012

RECOMMENDATION

For TAVI in patients with AS: PROHIBITIVE RISK

2. Patients who are not candidates for open heart surgery or for TAVI using femoral artery access may be considered for other alternative access procedures (eg, transapical, transaxillary, or transaortic)

(Conditional Recommendation, Low-Quality Evidence).

Canadian Journal of Cardiology
Volume 28 2012

RECOMMENDATION

For TAVI in patients with AS: HIGH RISK

3. TAVI is a reasonable alternative to SAVR for patients at high risk ("high risk" can be defined as a risk of mortality of 8% or major morbidity of 50% within 30 days of surgery as predicted by an experienced cardiac surgeon or by the STS risk calculator) of mortality or major morbidity and:

a. Duration and quality of life is likely to be significantly improved by treatment
b. Life expectancy with treatment is likely to exceed 1 to 2 years with treatment
c. There is a consensus amongst a multidisciplinary Heart Team including cardiologists and surgeons

(Strong Recommendation, High-Quality Evidence).

Canadian Journal of Cardiology
Volume 28 2012

RECOMMENDATION

For TAVI in patients with AS: LOW and INTERMEDIATE RISK

4. SAVR is the treatment of choice for patients diagnosed with severe symptomatic AS considered at intermediate or low surgical risk (Strong Recommendation, Moderate-Quality Evidence).

5. TAVI may be offered to selected patients with severe symptomatic AS who would otherwise be considered intermediate to low risk of mortality where there is a consensus of the Heart Team that they are at significantly increased risk of either morbidity or mortality due to special circumstances (eg, frailty, very advanced age, patent bypass grafts, multivalve disease, etc)

(Conditional Recommendation, Low-Quality Evidence).

Canadian Journal of Cardiology
Volume 28 2012

Our pathway to TAVI

Patients selection

HEART TEAM

Cardiologist

Heart Surgeon

Anaesthesiologist

Imaging specialist

Radiologist

Geriatrist

Pulmonologist

Vascular surgeon

RISK SCORES
COMORBIDITIES

RISK SCORE

- ✓ EUROSCORE Logistic
- ✓ EUROSCORE Standard
- ✓ **EUROSCORE II**
- ✓ STS score

PROCEDURAL SUCCESS

- LEE score
- ADL score
- 15 feets walking test
- Prension test

FRAILTY

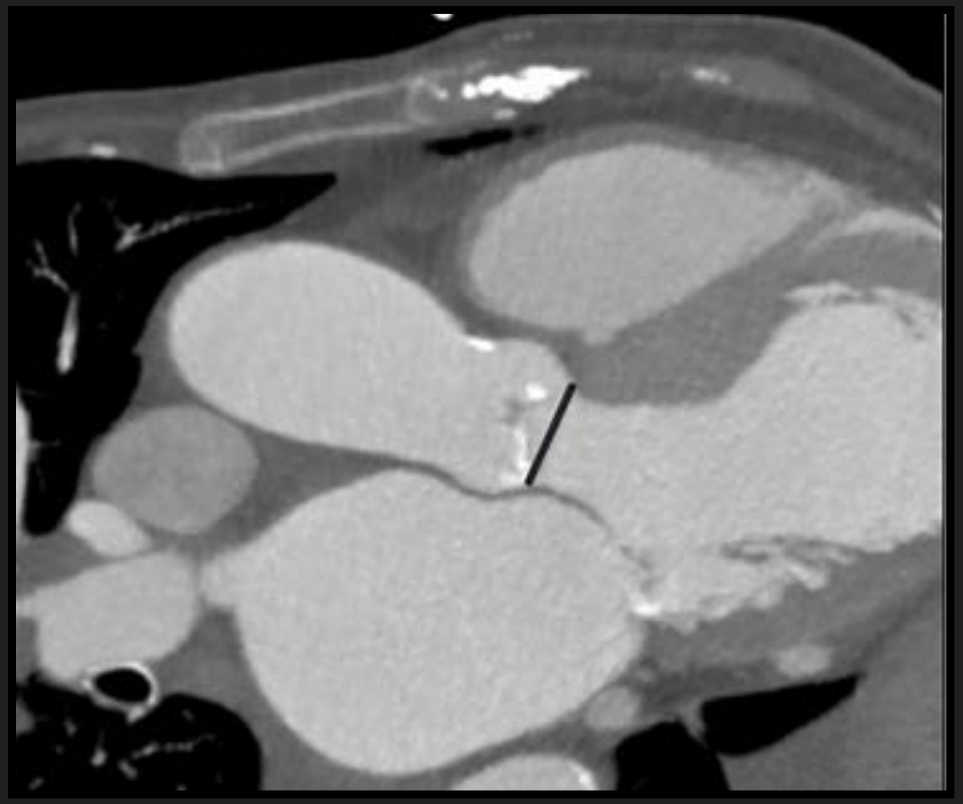
IMAGING

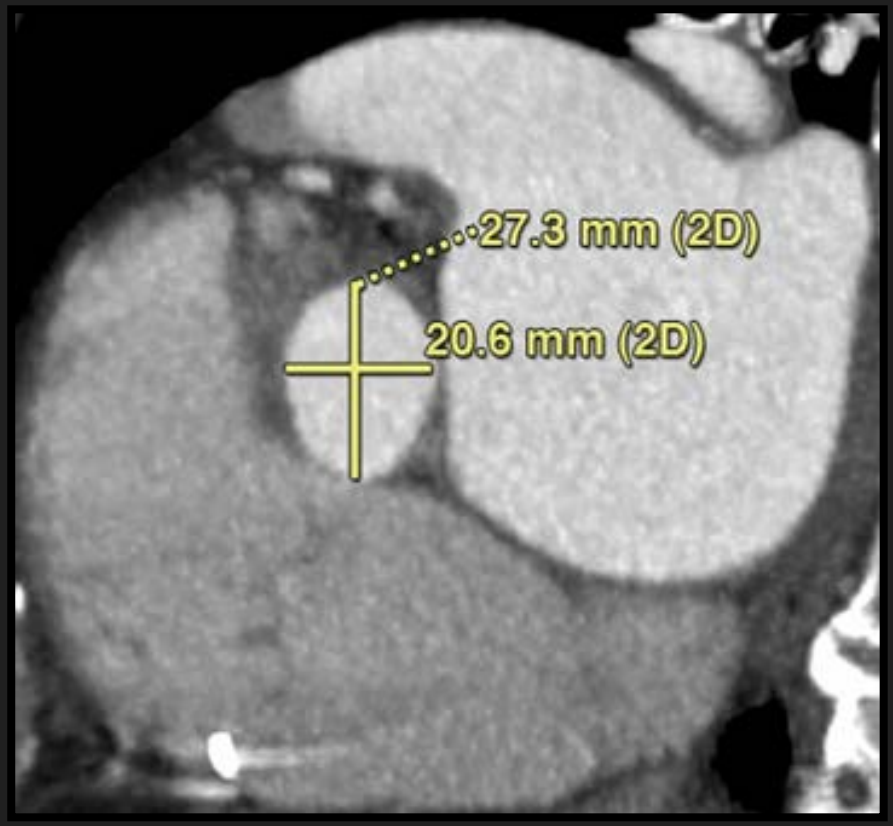
- ✓ **Multidetector Computed Tomography**
  64 slides cardiac gated
- ✓ **Echocardiography** *(TTE and TEE)*
- ✓ **Angiography**

Multidetector Computed Tomography

- **Anulus** morphology and dimension (3D)
- **Aortic root** morphology and dimension (3D)
- **Coronary ostia**
- **Ascending Aorta and aortic arch)**
- **Subclavian access**
- **Abdominal and thoracic Aorta**
- **Iliofemoral access**

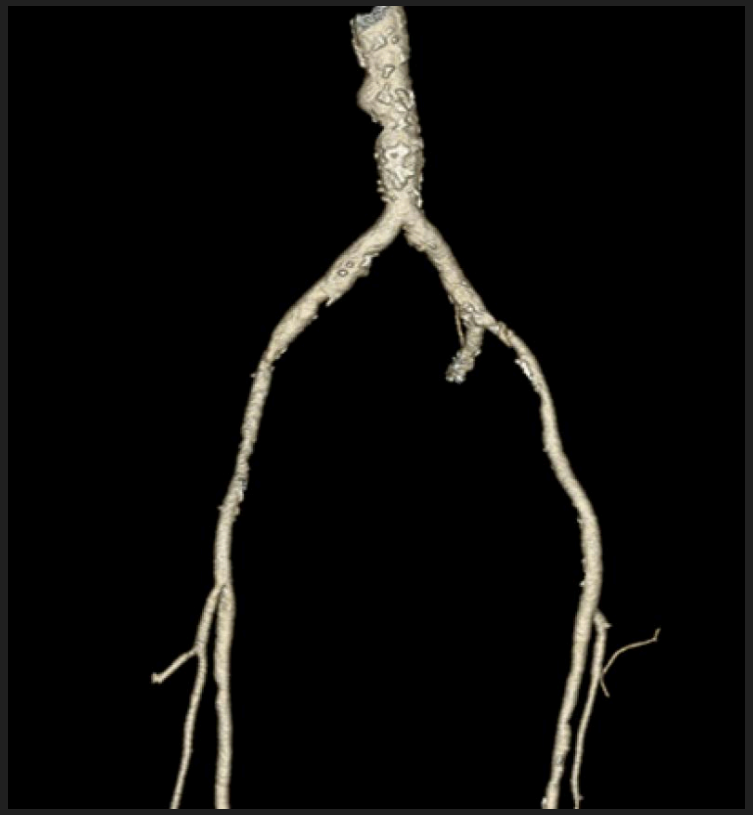
Multidetector Computed Tomography

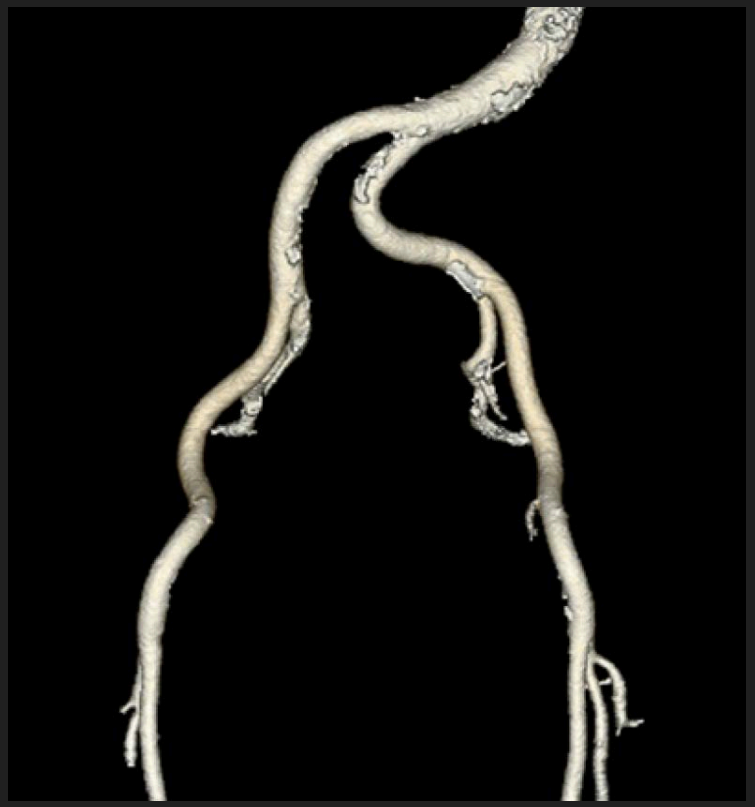




Multidetector Computed Tomography

Iliofemoral access



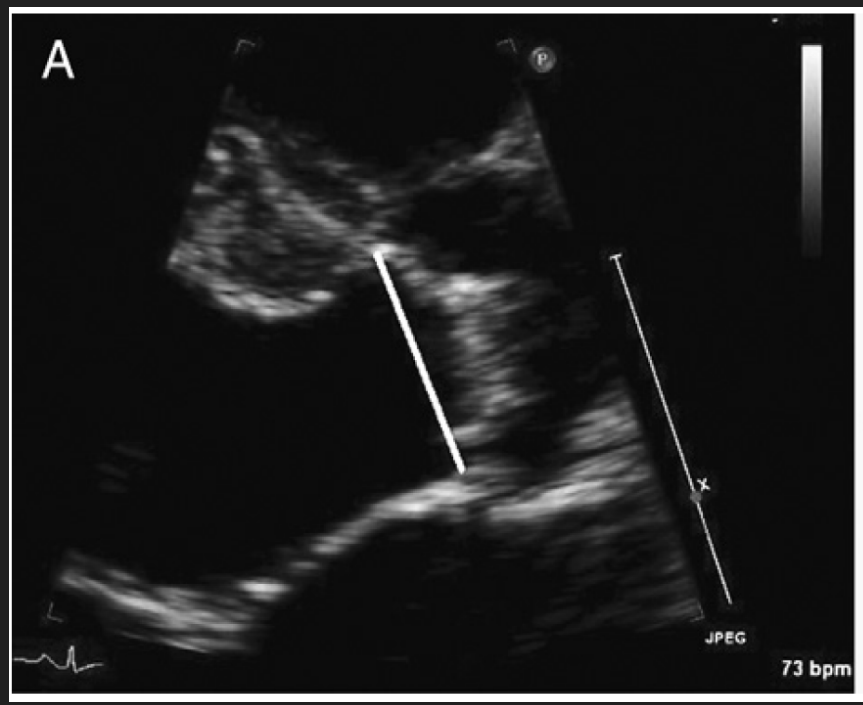


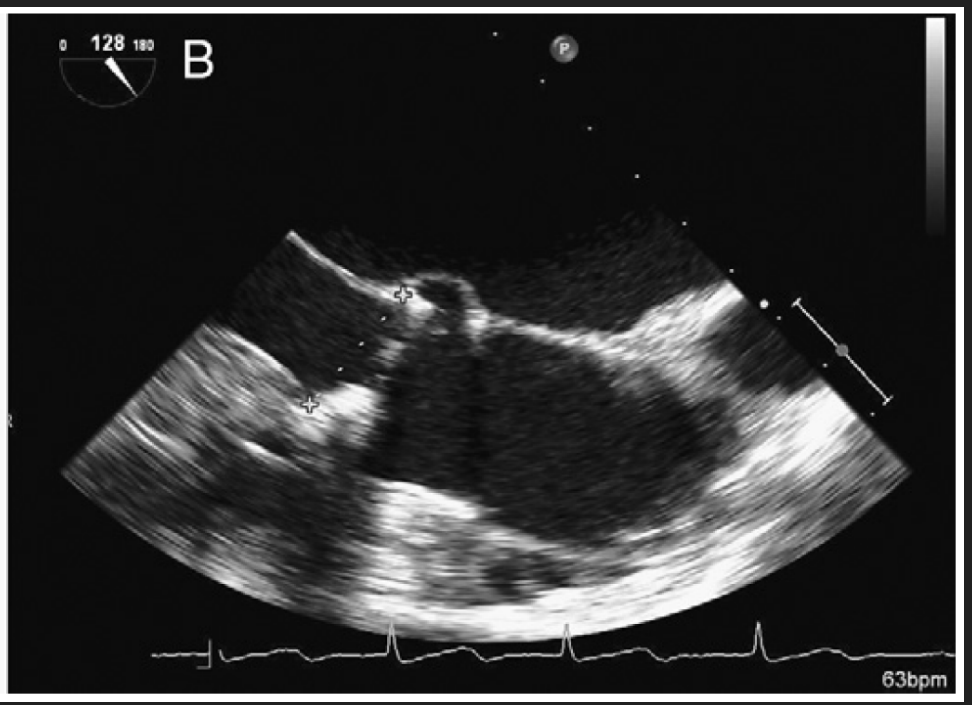
J Am Coll Cardiol Img2011;4:416–29

Echocardiography

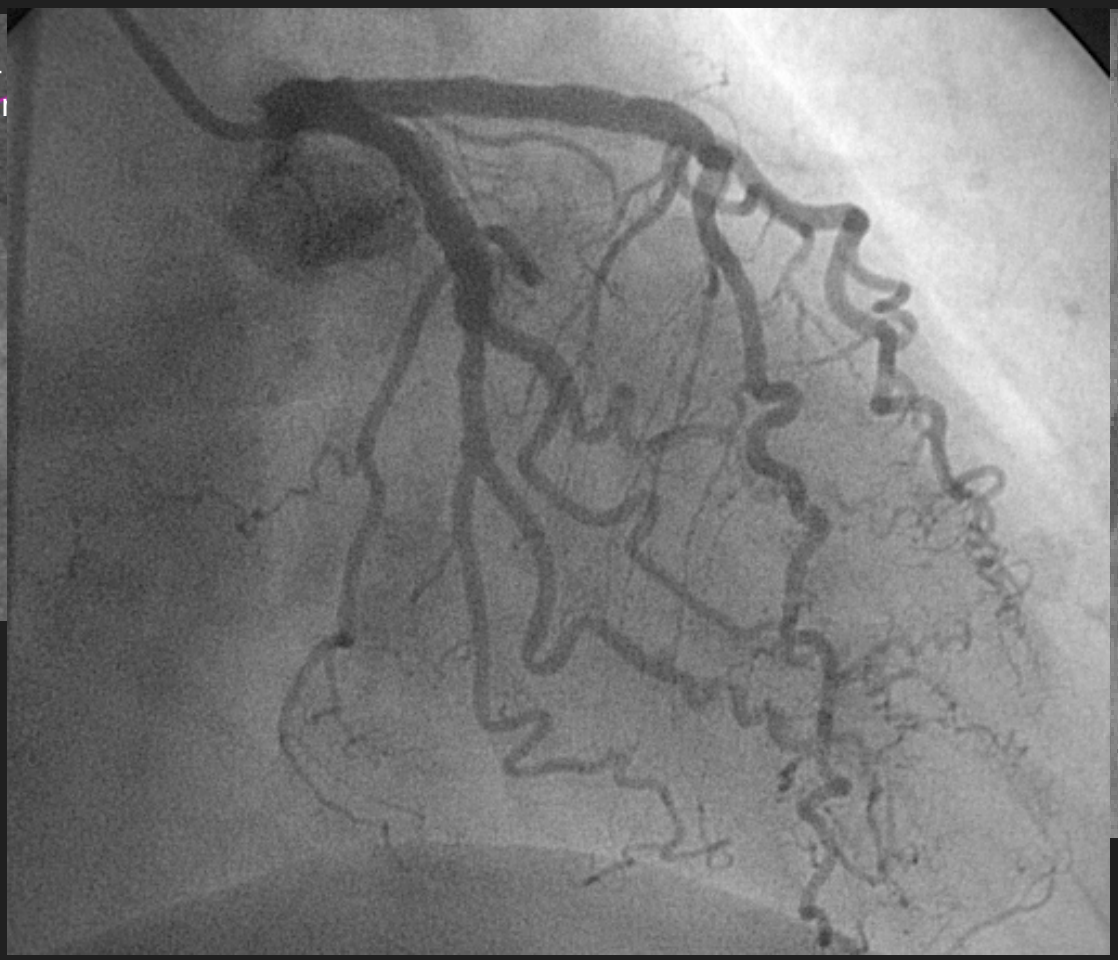
- Anular dimension
- Cusps (number, mobility, thickness)
- Calcifications
- Aortic regurgitation
- LV and RV dimension and function
- Basal septal hypertrophy

Echocardiography





Angiography



HEART TEAM

Is TAVI possible for the patient?

If yes:

Wich Kind of valve?

Wich Kind of access?

WICH VALVE?

Edwards Sapien Valve

- Transfemoral
- Transapical

CoreValve – Medtronic

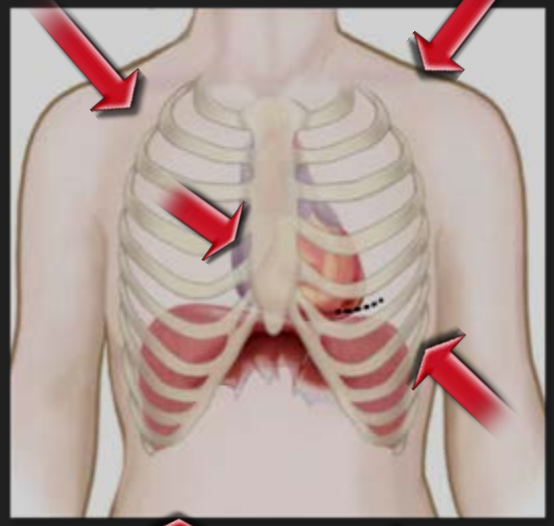
- Transfemoral
- Transubclavian
- Transaorta

ACCESS

Right Subclavian

Left Subclavian

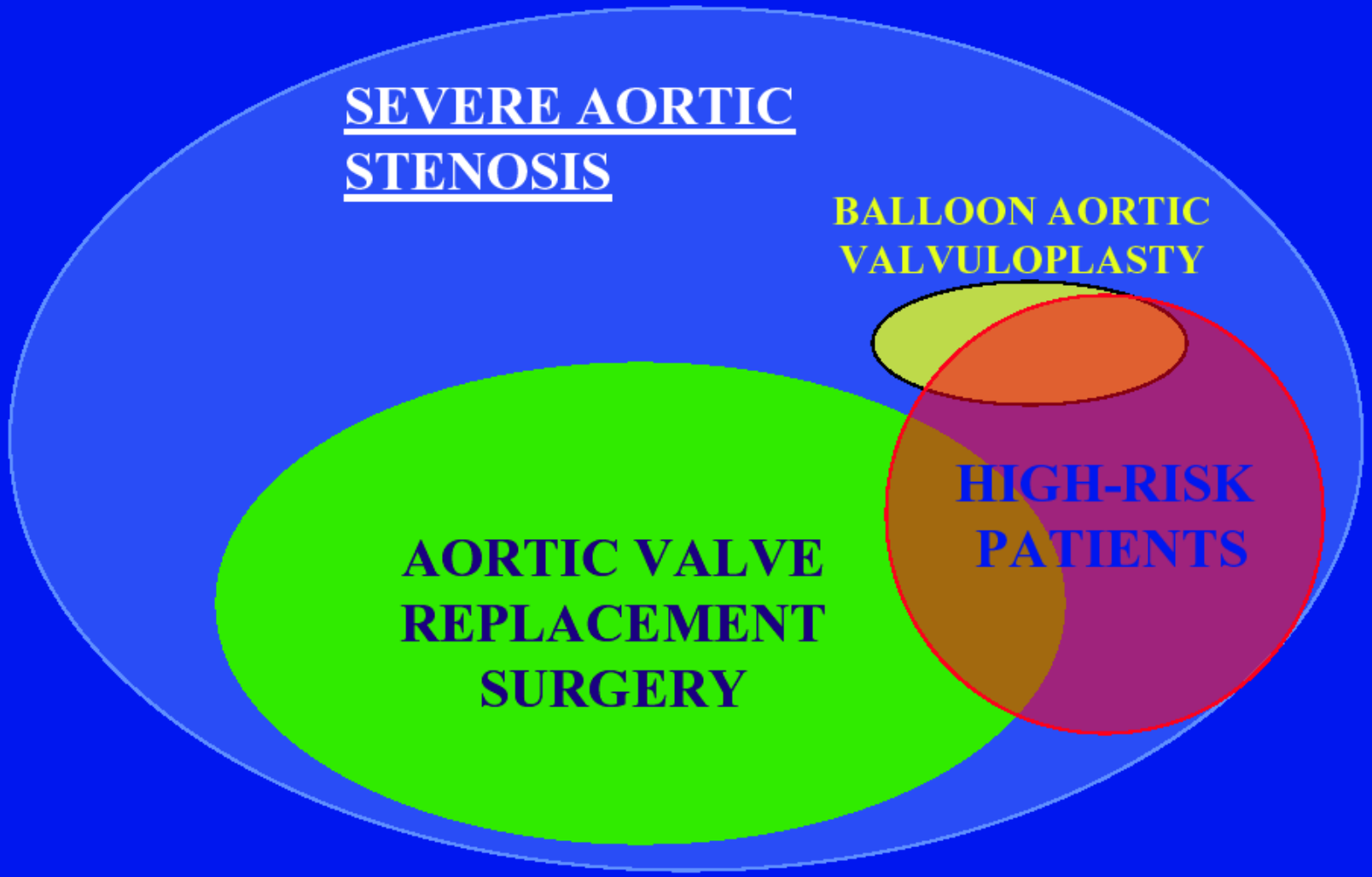
Trans aorta

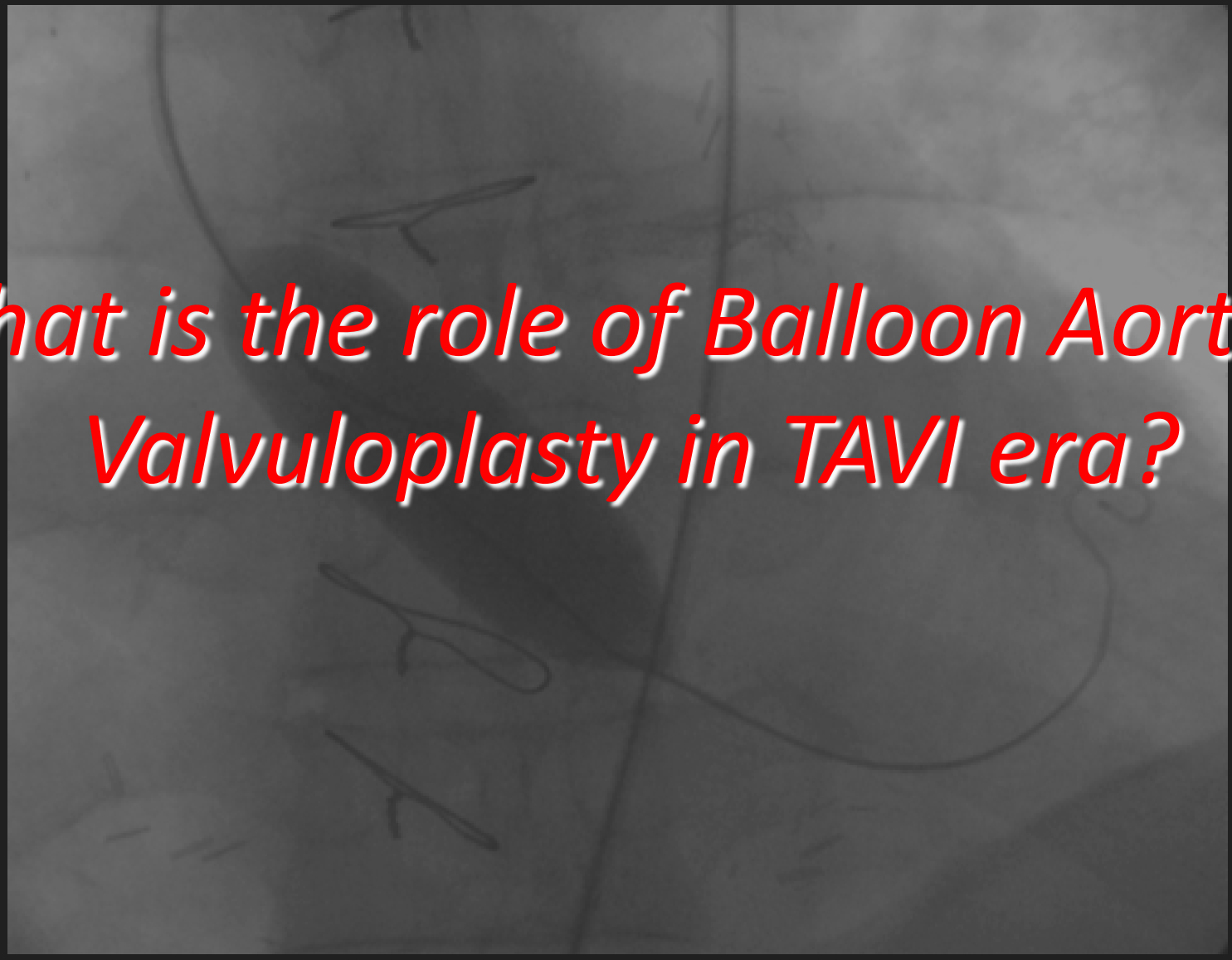


Transapical

Transfemoral

Severe Aortic Stenosis: Therapy




What is the role of Balloon Aortic Valvuloplasty in TAVI era?

Balloon Aortic Valvuloplasty

TODAY IN OUR CENTER

1. Palliation in *"too sick"* patients with serious comorbid conditions (life expentancy < 1 y…)

2. Patients who require urgent non cardiac surgery (cancer, aortic aneurysm…)

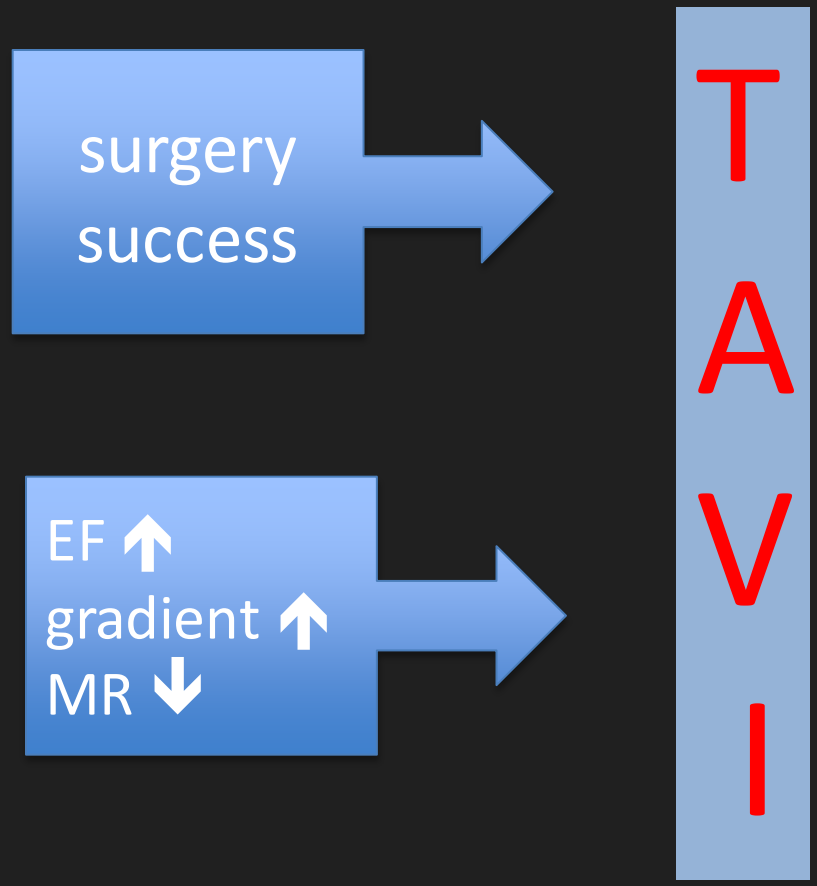
3. A bridge to surgery in hemodynamically unstable patients who are at high risk for AVR

4. A bridge to TAVI in hemodynamically unstable patients

5. Unstable patients (end-stage HF…)

BAV “to” TAVI

- Urgent non cardiac surgery
- low EF and/or low gradient and/or moderate MR

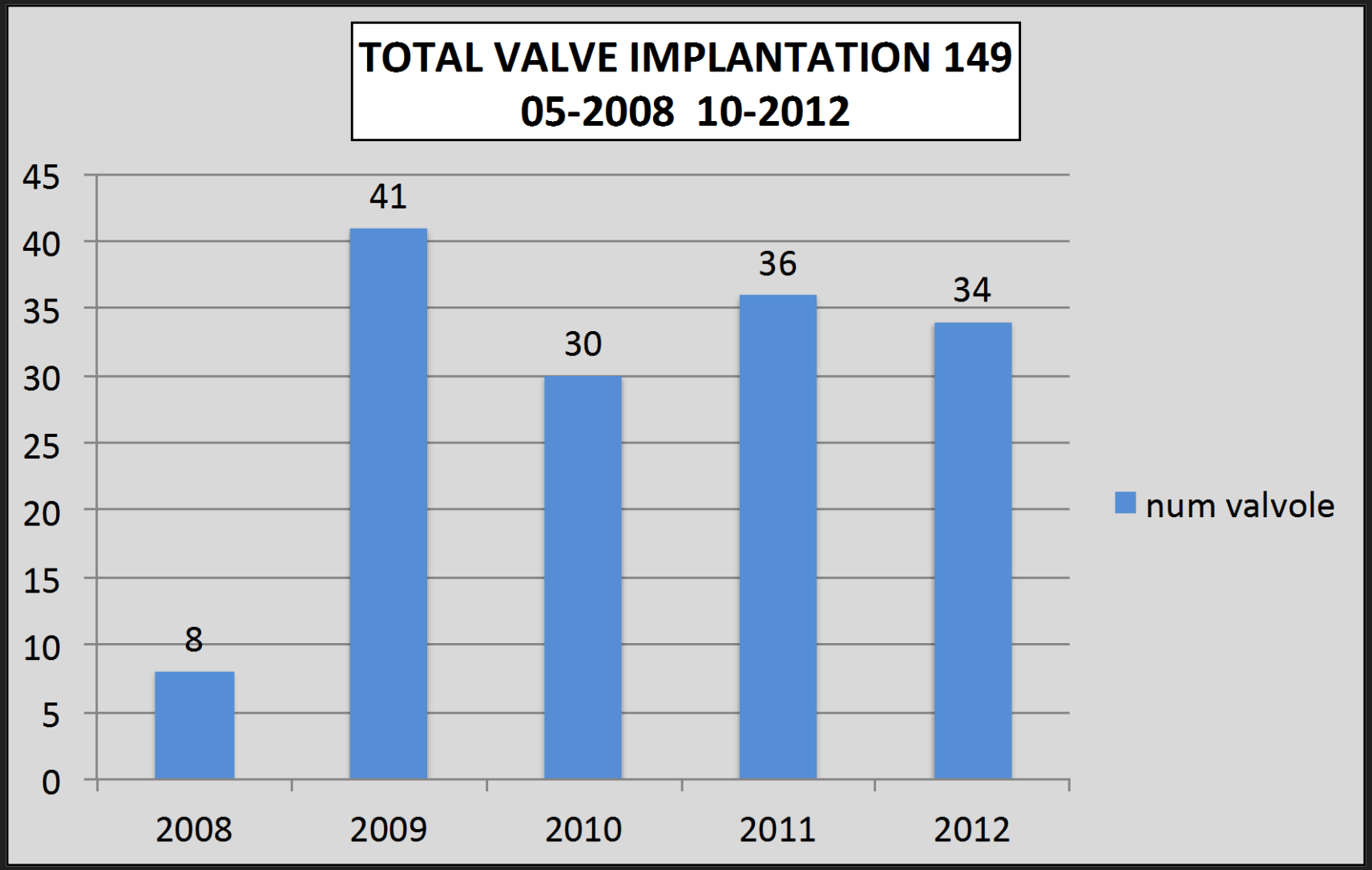


Molinette Hospital experience with....

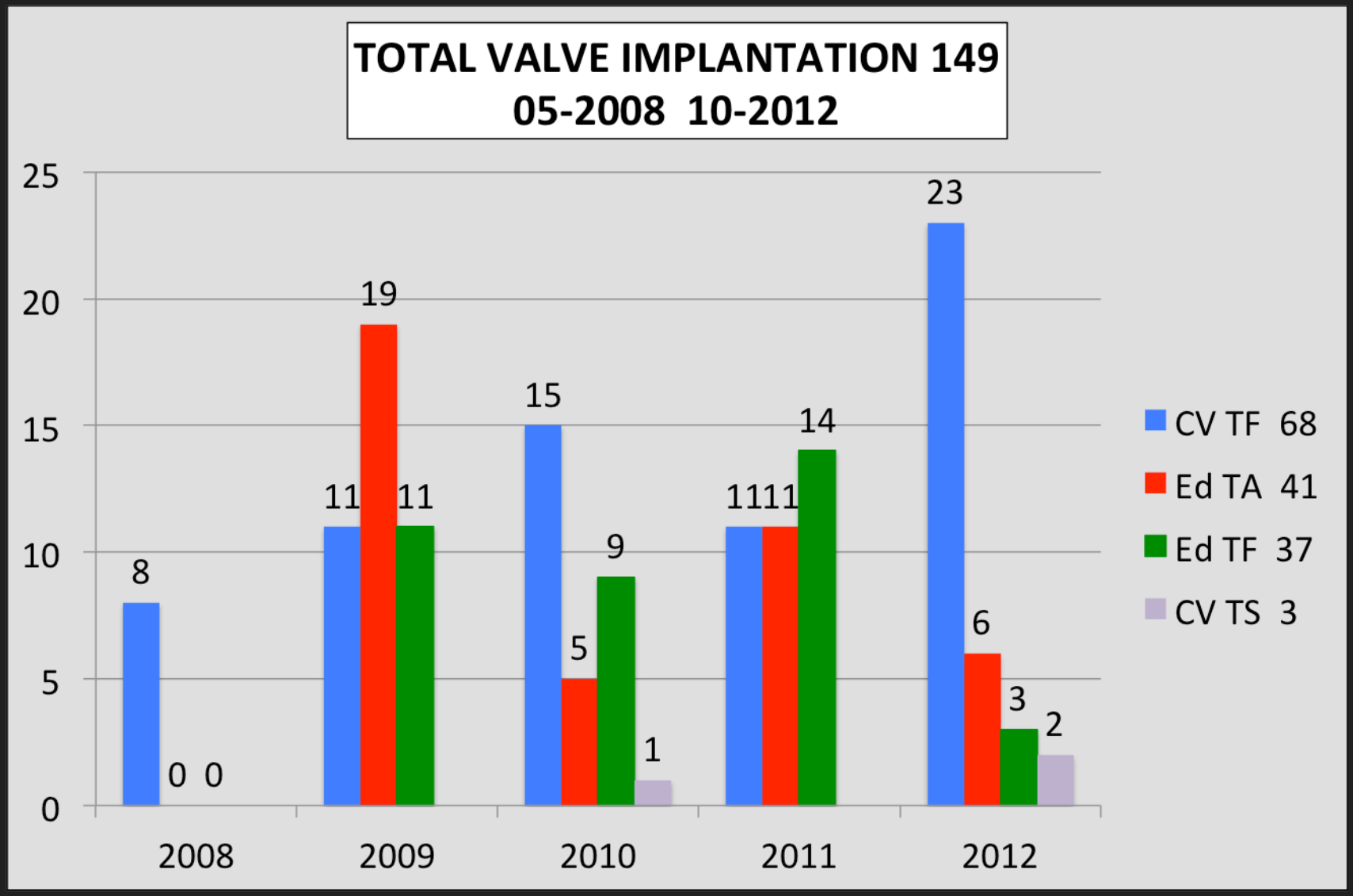
Transcatheter aortic-valve implantation

RESULTS

CLINICAL EXPERIENCE



CLINICAL EXPERIENCE

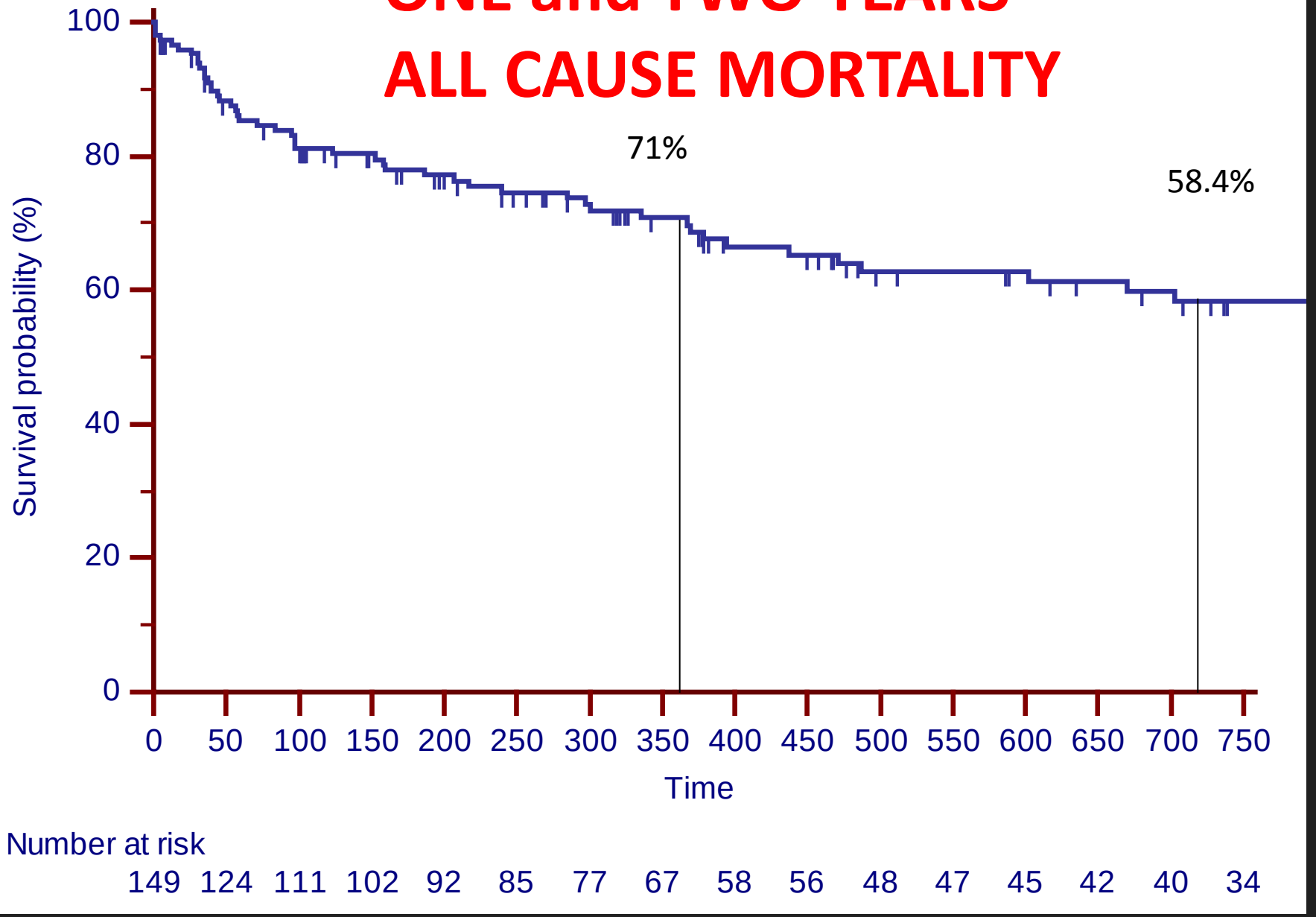


CLINICAL EXPERIENCE

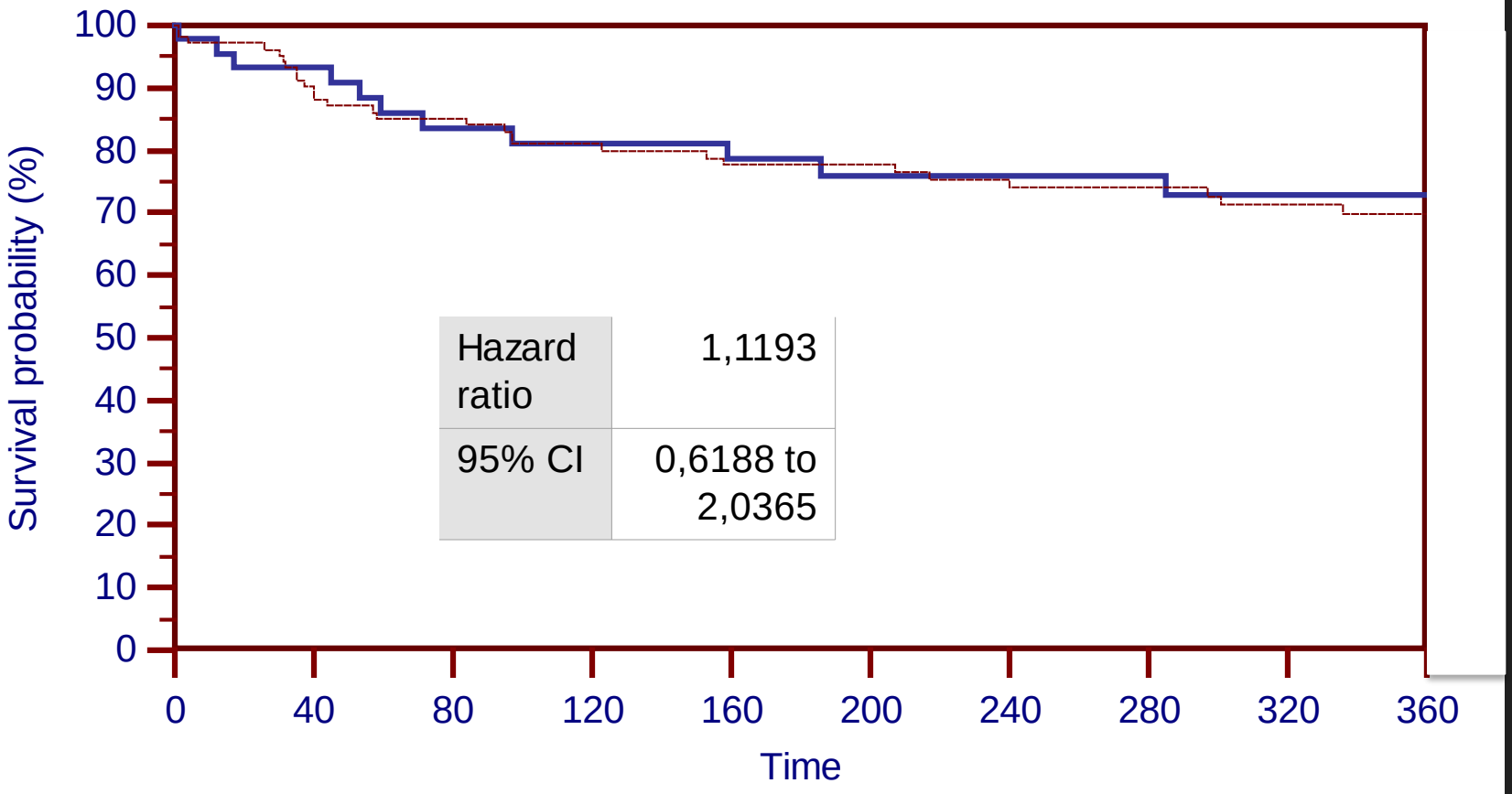
Age	82,4 ± 6,4
Female sex	91 (61,0%)
Log euroSCORE	21,08 ± 12,13%
Euroscore II	7.53 ± 6,23 %
STS score mortality	8,5 ± 5,9%
NYHA ≥III	109 (70,5%)
Previous cardiac surgery	20 (13,4%)
Previous PCI	56(37,6%)
Previous aortic valvuoplasty	13(8,7%)
Moderate and severe COPD	39 (26,2%)
Creatinine Clearance < 60 mg/dl	95 (82,6%)
Cancer	24 (16,1%)

MORTALITY

ONE and TWO YEARS ALL CAUSE MORTALITY



TF vs TA ONE YEAR ALL CAUSE MORTALITY



Number at risk

Group: 0	44	40	34	32	31	27	27	25	24	21
Group: 1	105	87	83	74	68	65	60	56	50	46

CLINICAL EXPERIENCE

MORTALITY

ALL CAUSE MORTALITY 34,2% (51/149)

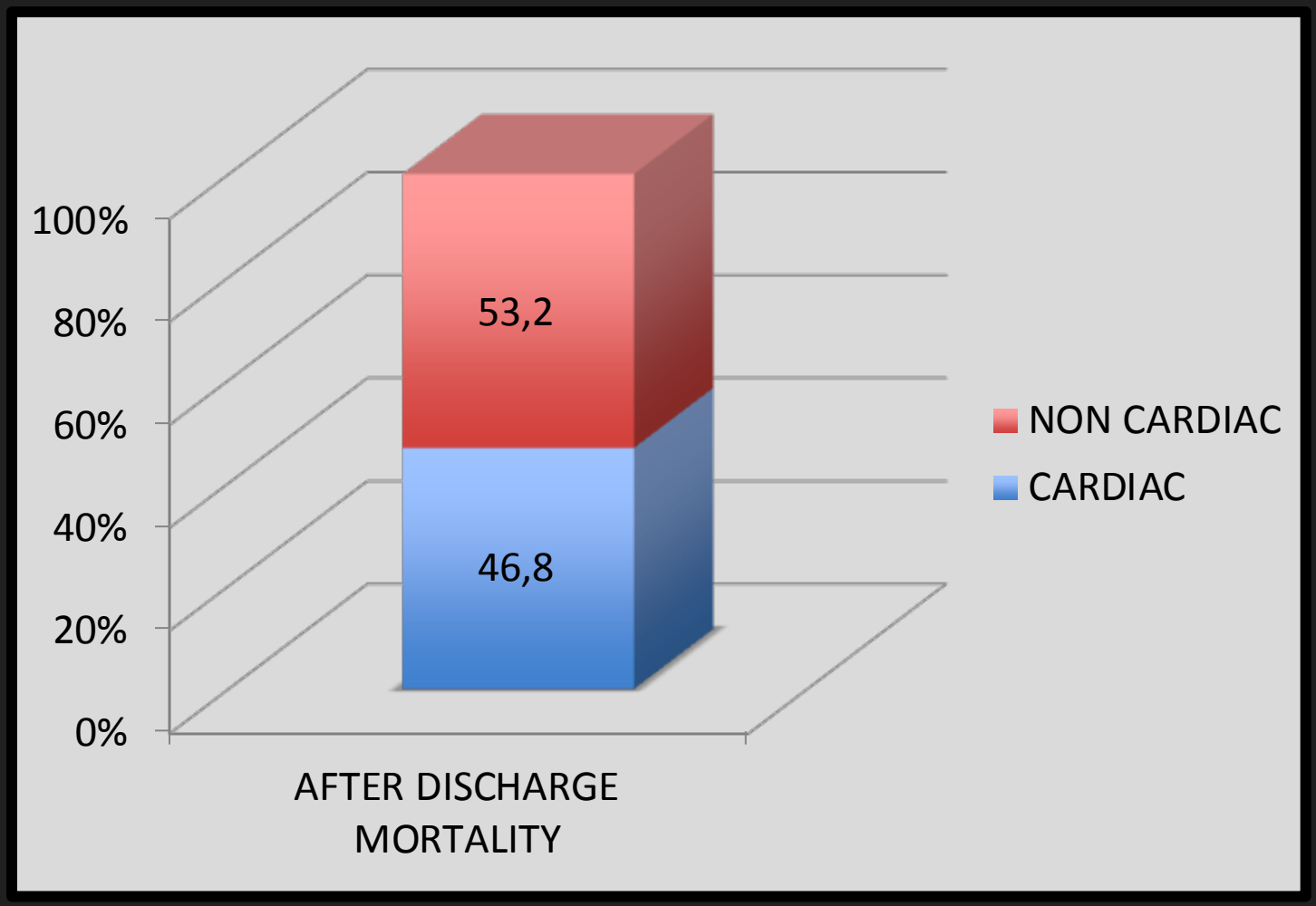
VARC 30 DAYS MORTALITY 12,7% (19/149)

AFTER DISCHARGE MORTALITY 21,0% (32/149)

Mean Follow-up 1,2 ys ± 414 days

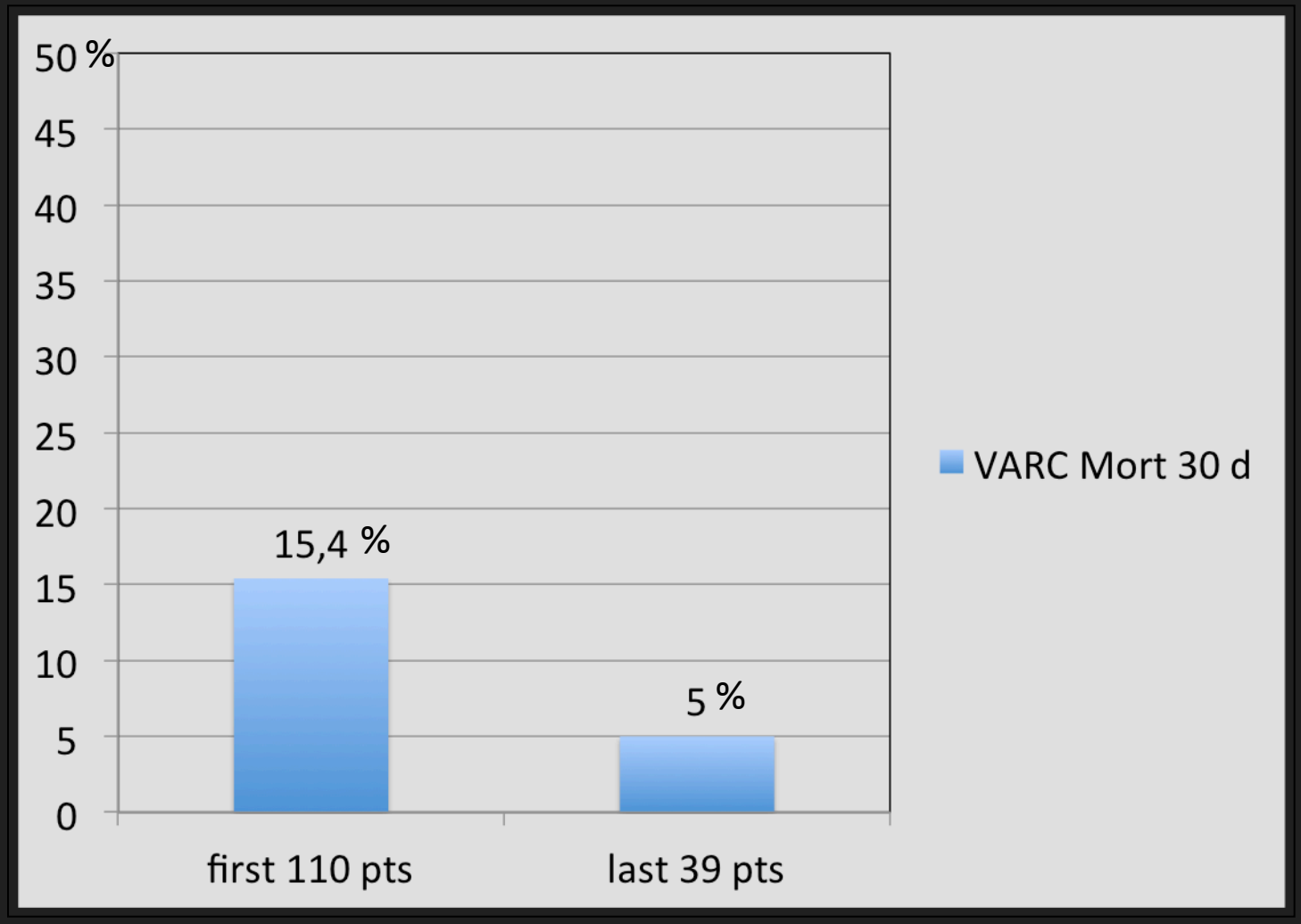
AFTER DISCHARGE MORTALITY

Cardiac vs non cardiac



VARC MORTALITY 30 DAYS

May 2008-October 2011 vs October 2011-October 2012



p 0.07

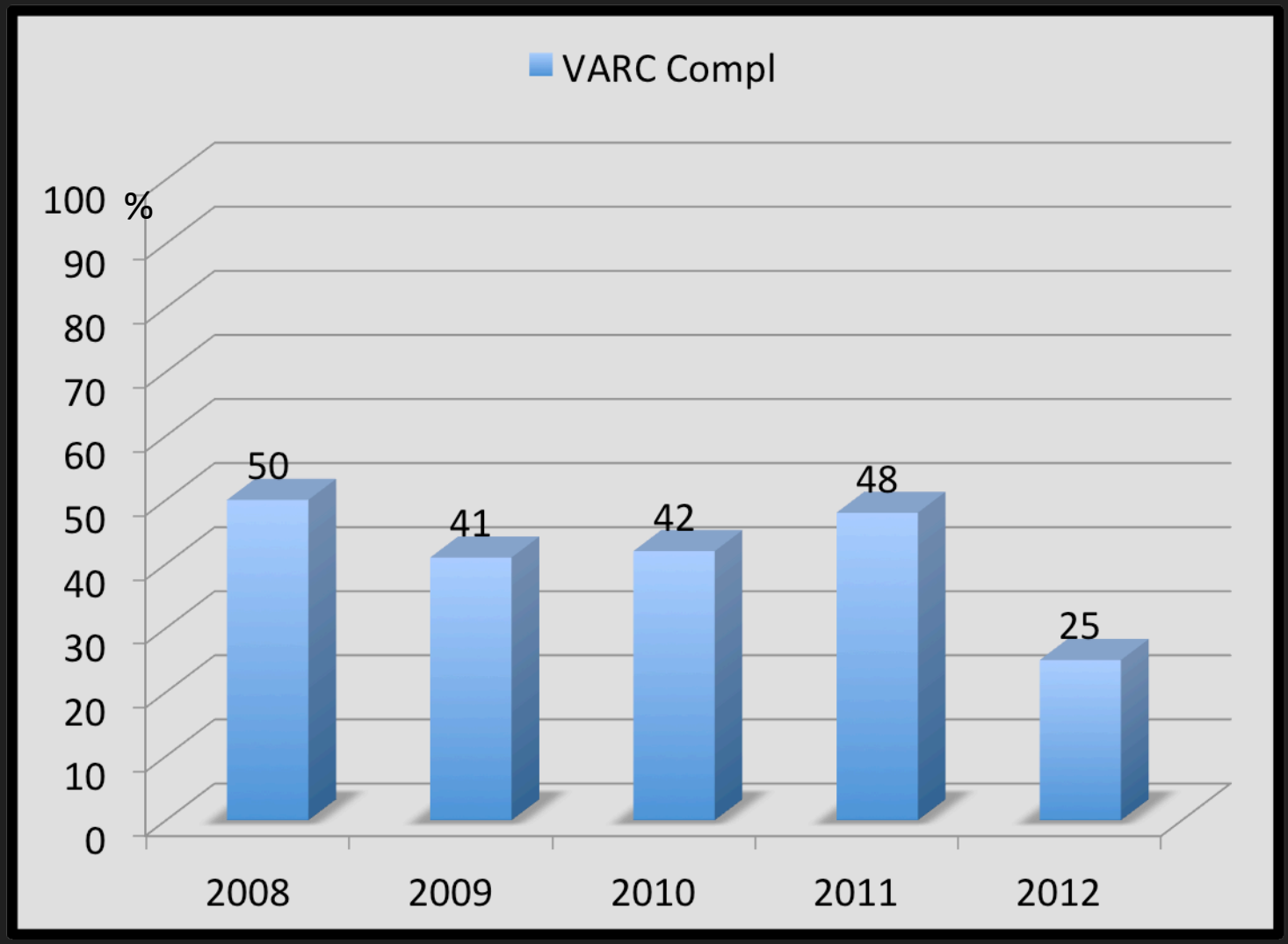
COMPLICATIONS

Vascular complications (VARC) Major and Minor

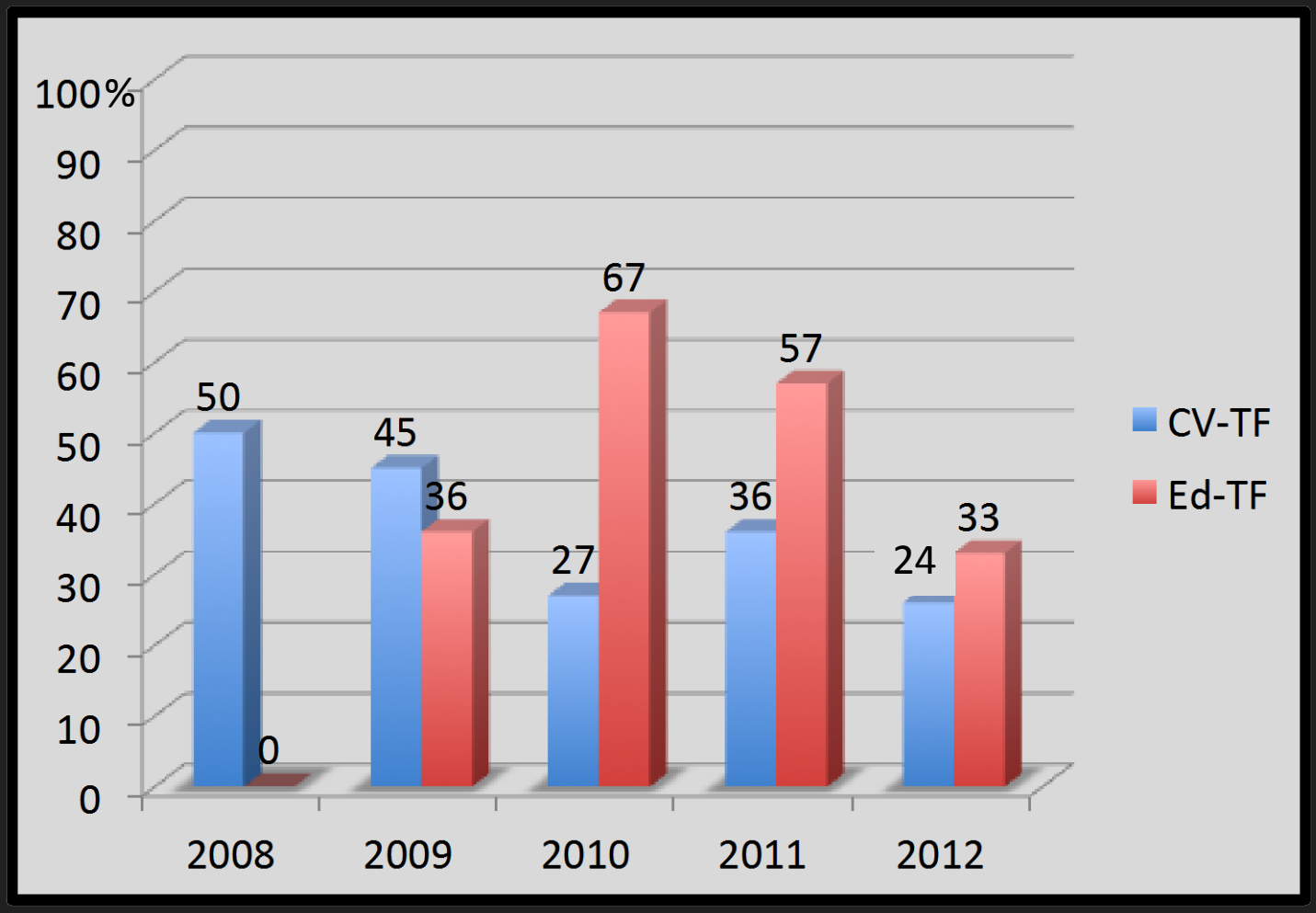
Total 38% (42/108)

- Major 26% (29/108)
- Minor 12% (13/108)

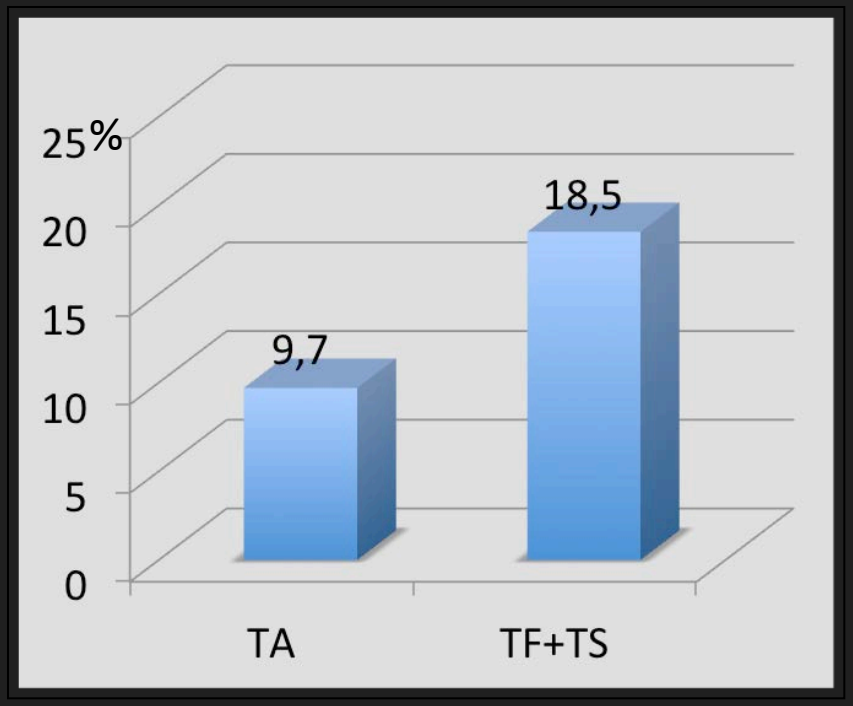
Vascular complications (VARC) Major and Minor

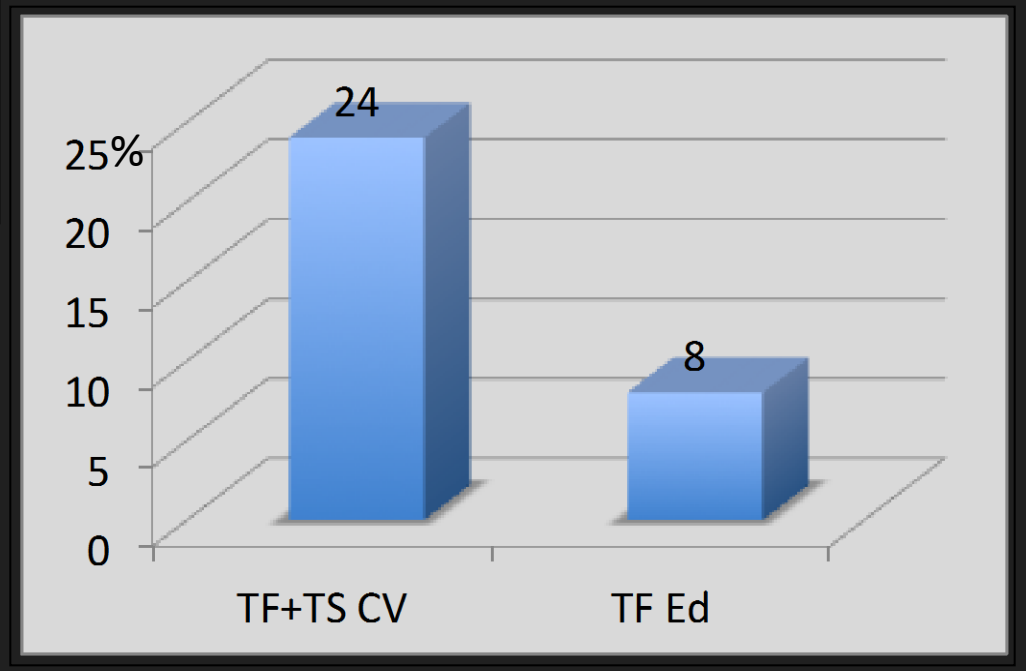


Vascular complications (VARC) Major and Minor CV vs Ed per year



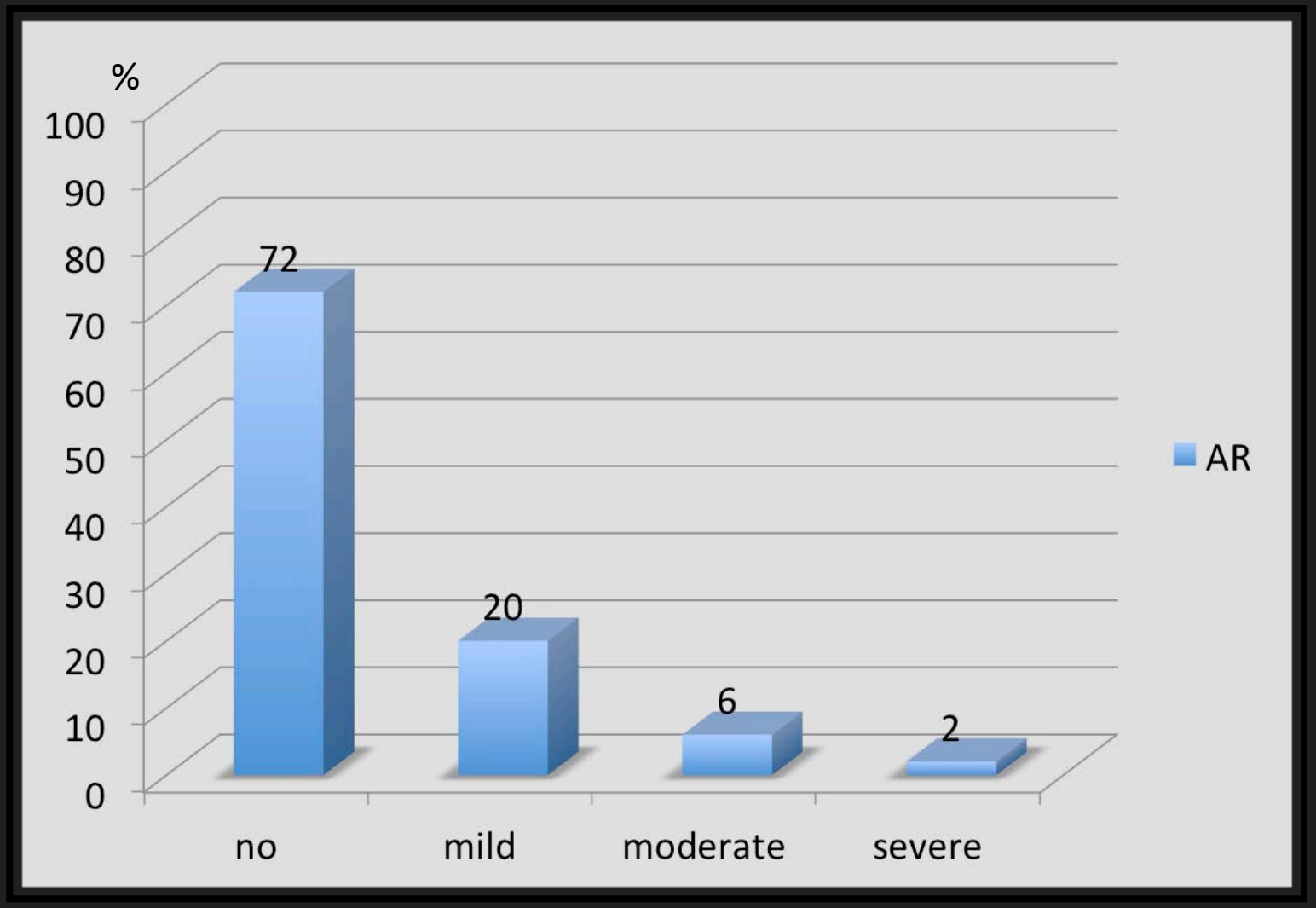
Post procedure PM implantation





Residual Aortic Regurgitation

Pre-discharge echocardiography



CEREBROVASCULAR COMPLICATIONS

TIA: 2%

Minor Stroke: 0,6%

Mayor Stroke: 5,4%

CLINICAL FOLLOW-UP

NYHA I 25%

NYHA II 68,4%

NYHA III 6,6%

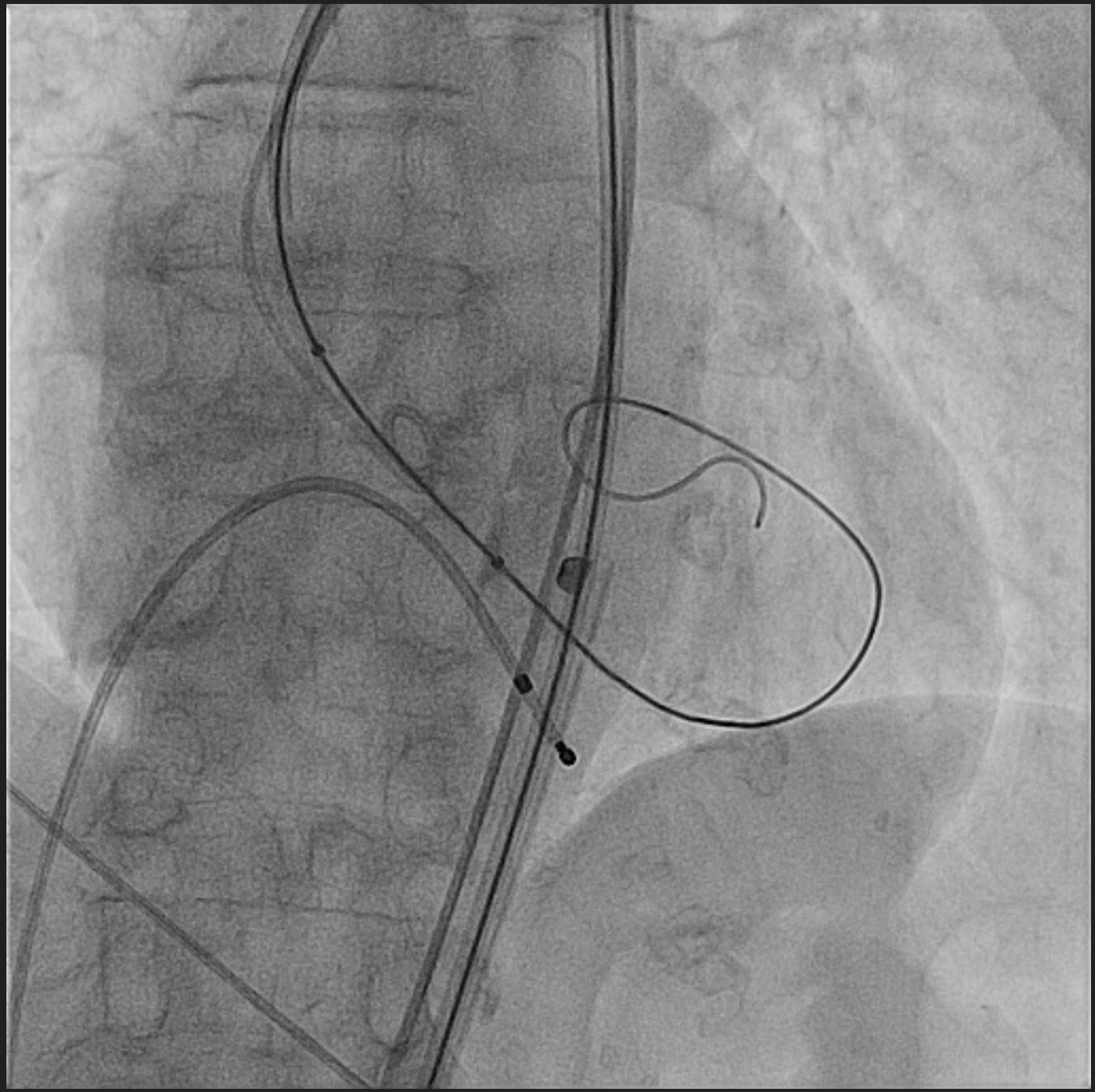
PROCTORs

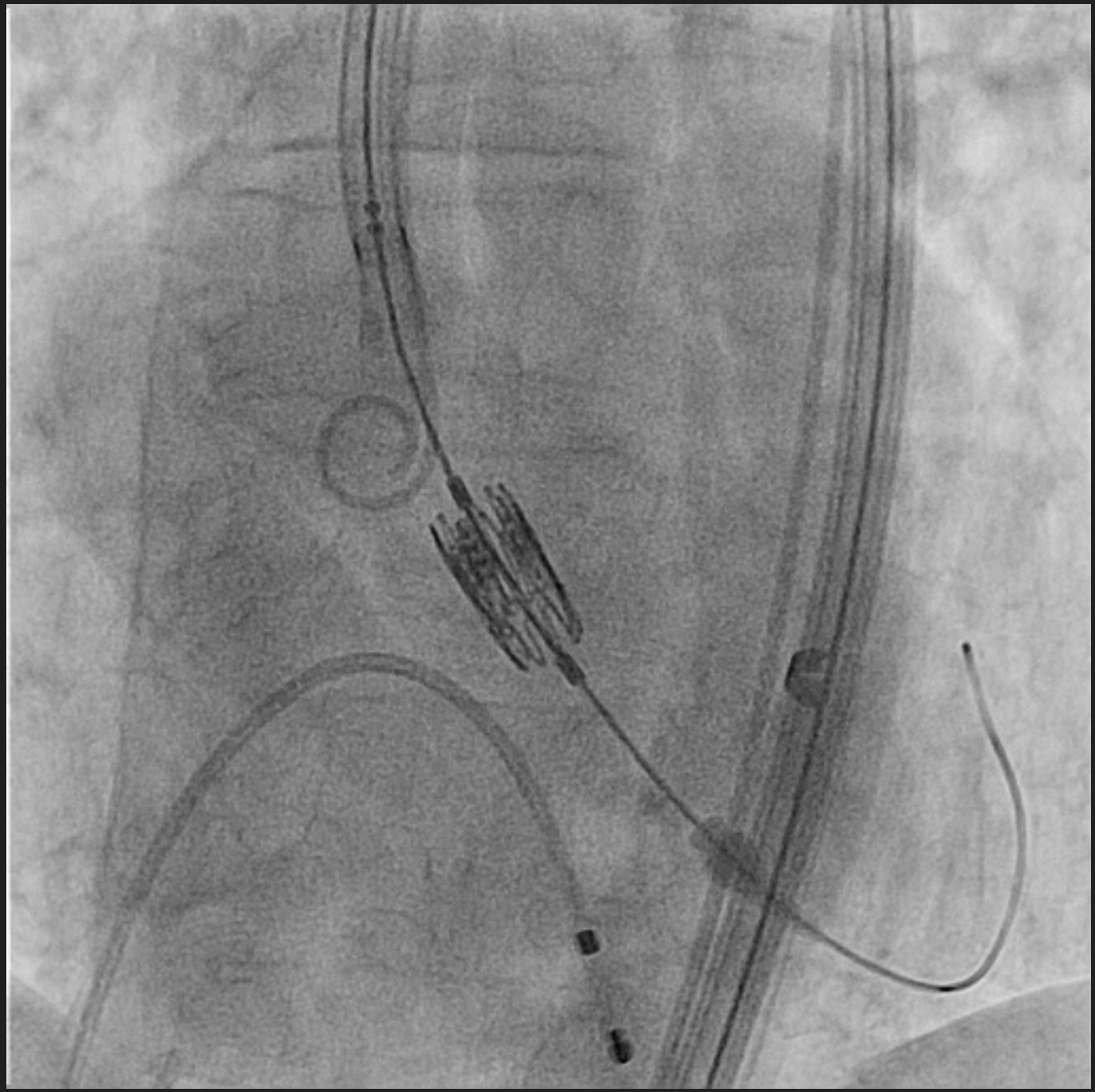
J. C. Laborde
P. De Jager
G.P. Ussia
A. Ramondo
F. Ettori
F. Bedogni

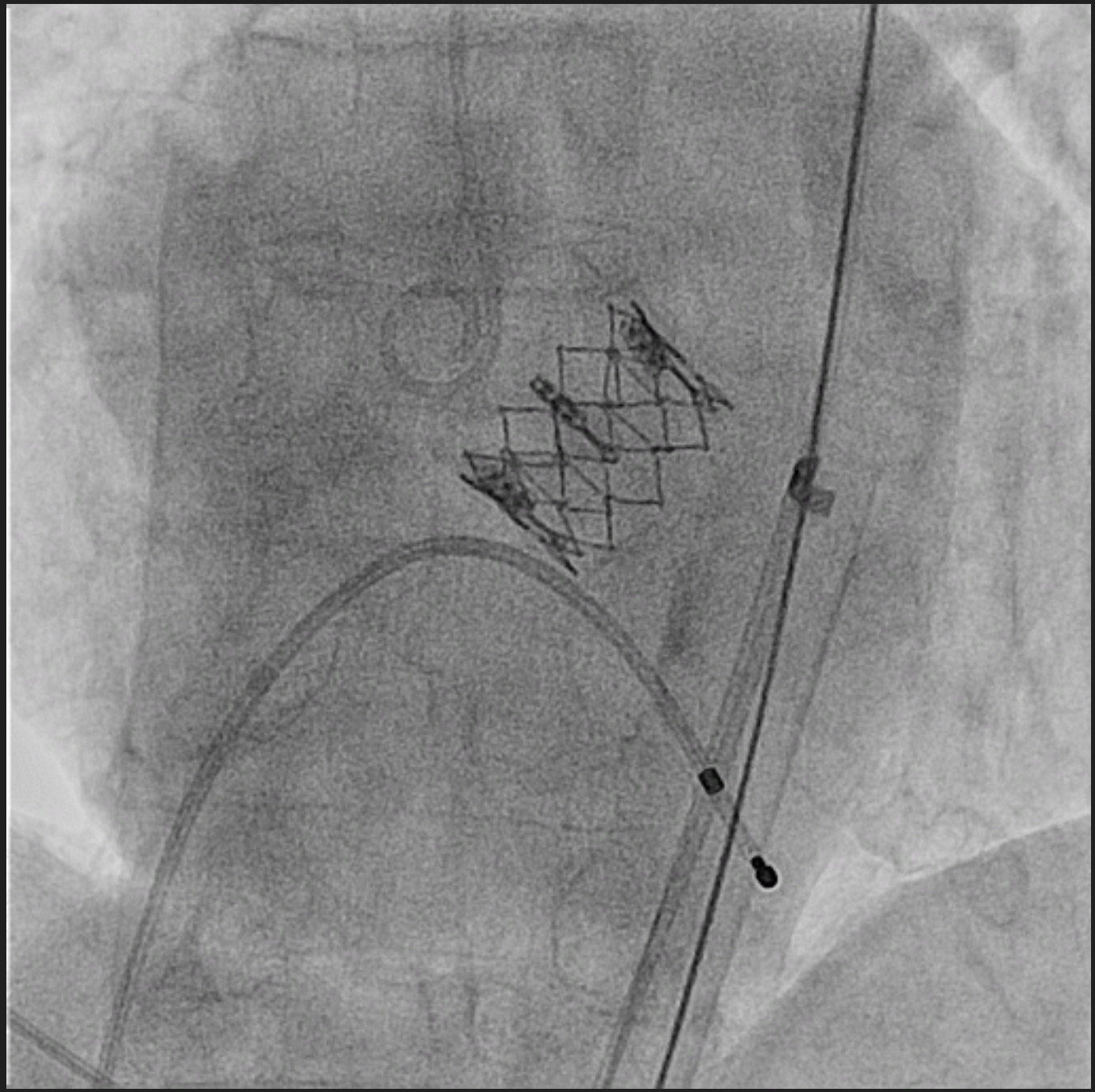
A.Garcia
A.Colombo
D. Imbert
Y. Almagor

V. Bapat
A.El Gamel

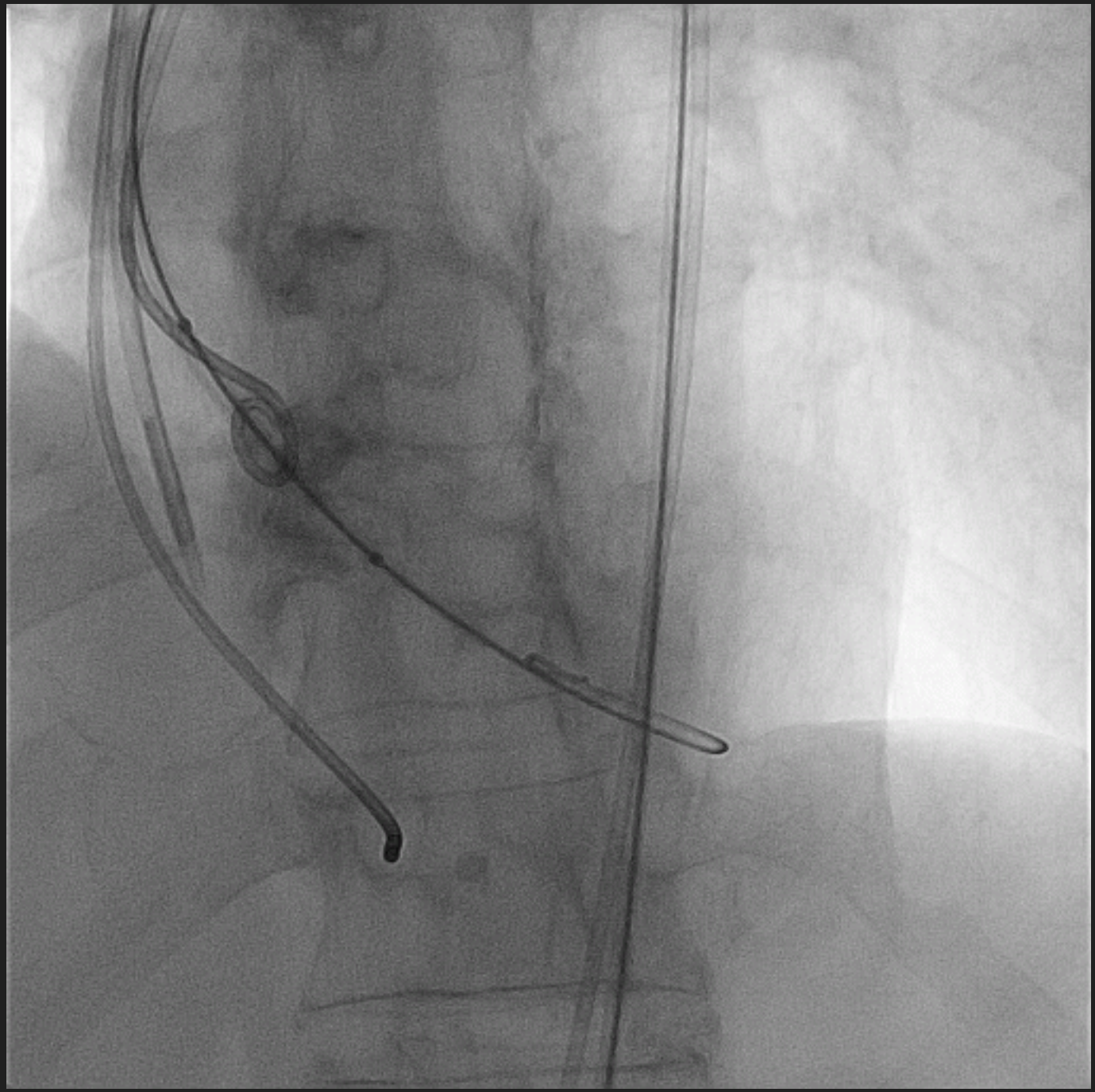
Transfemoral Edwards

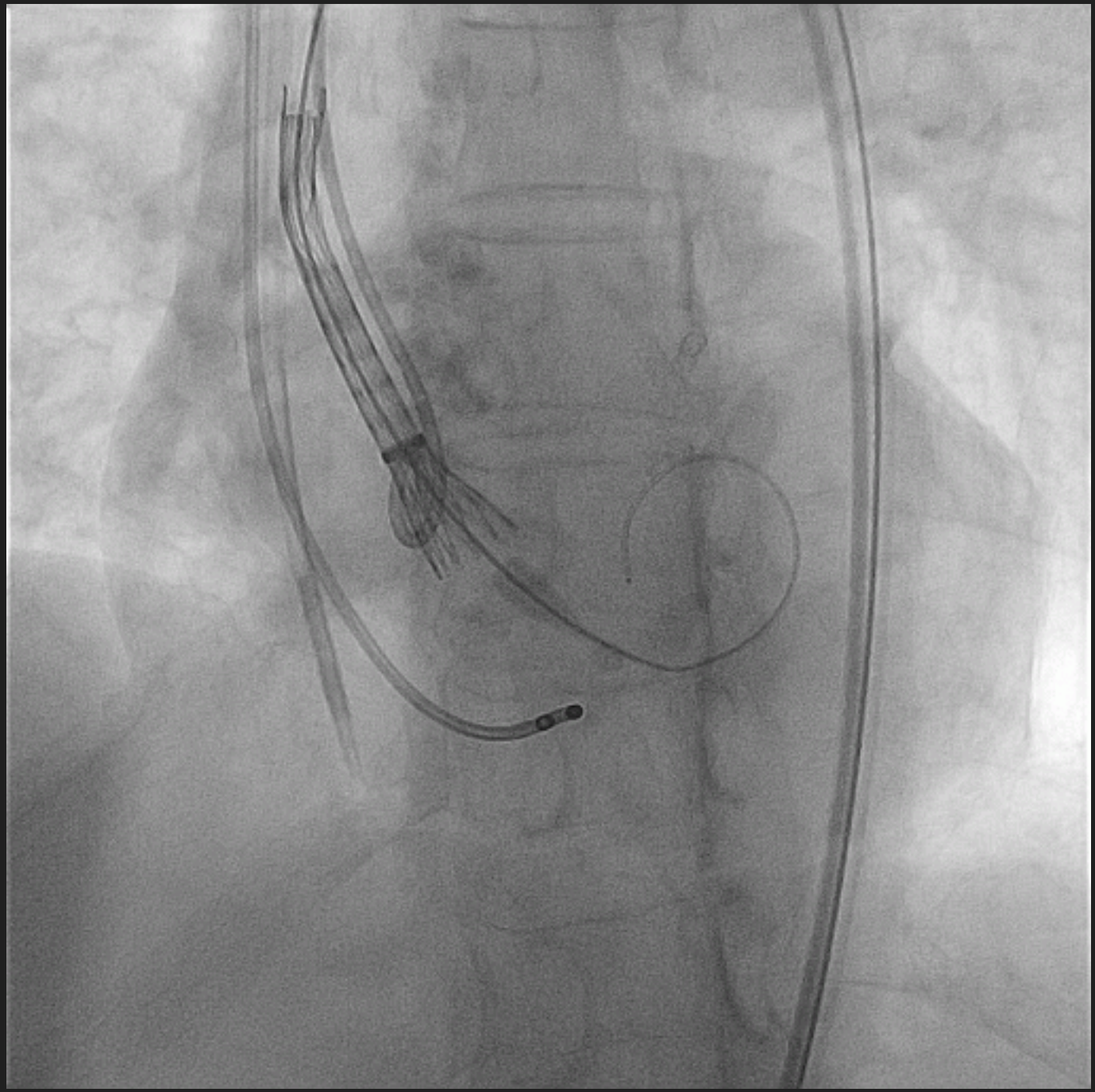


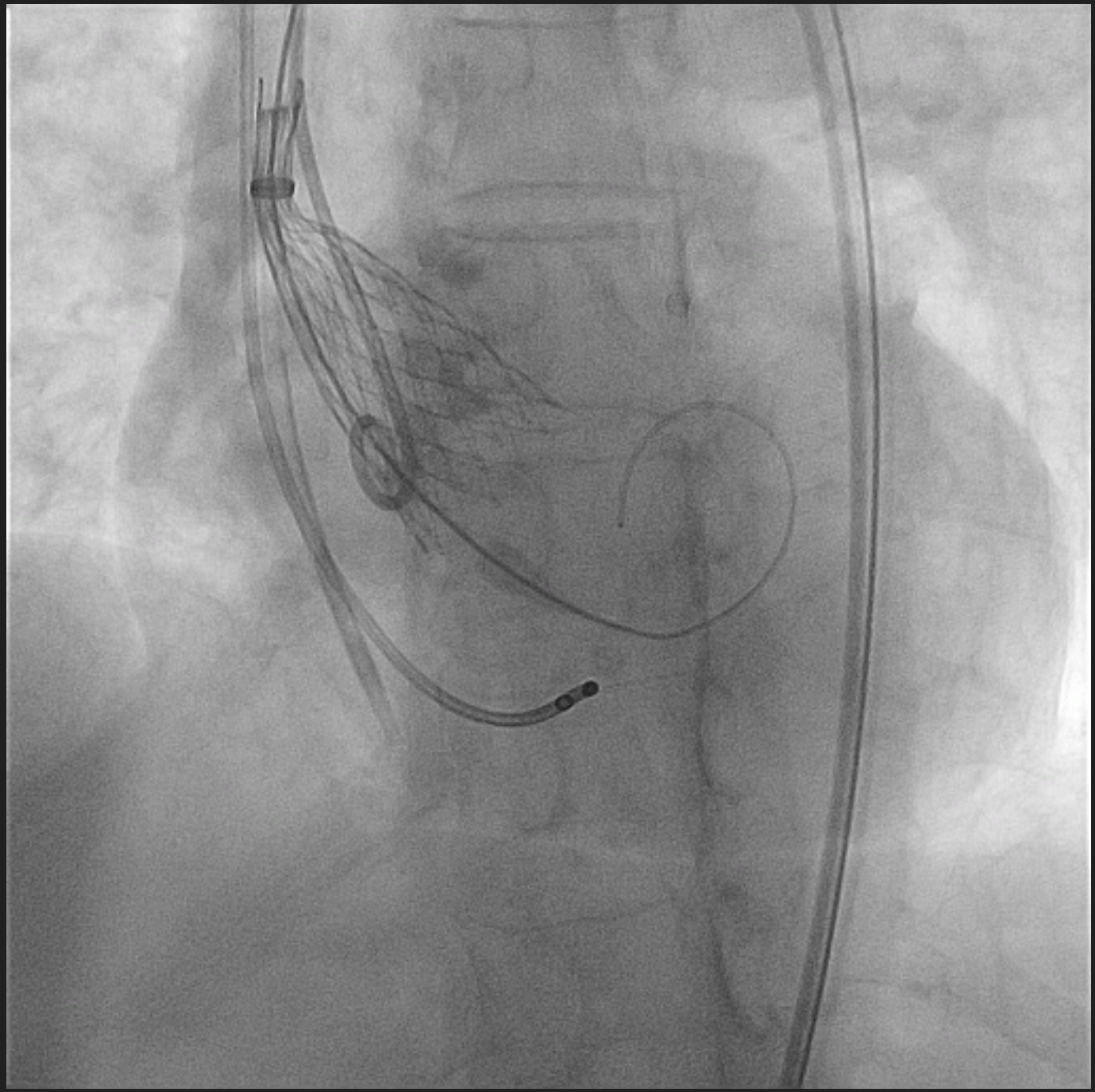


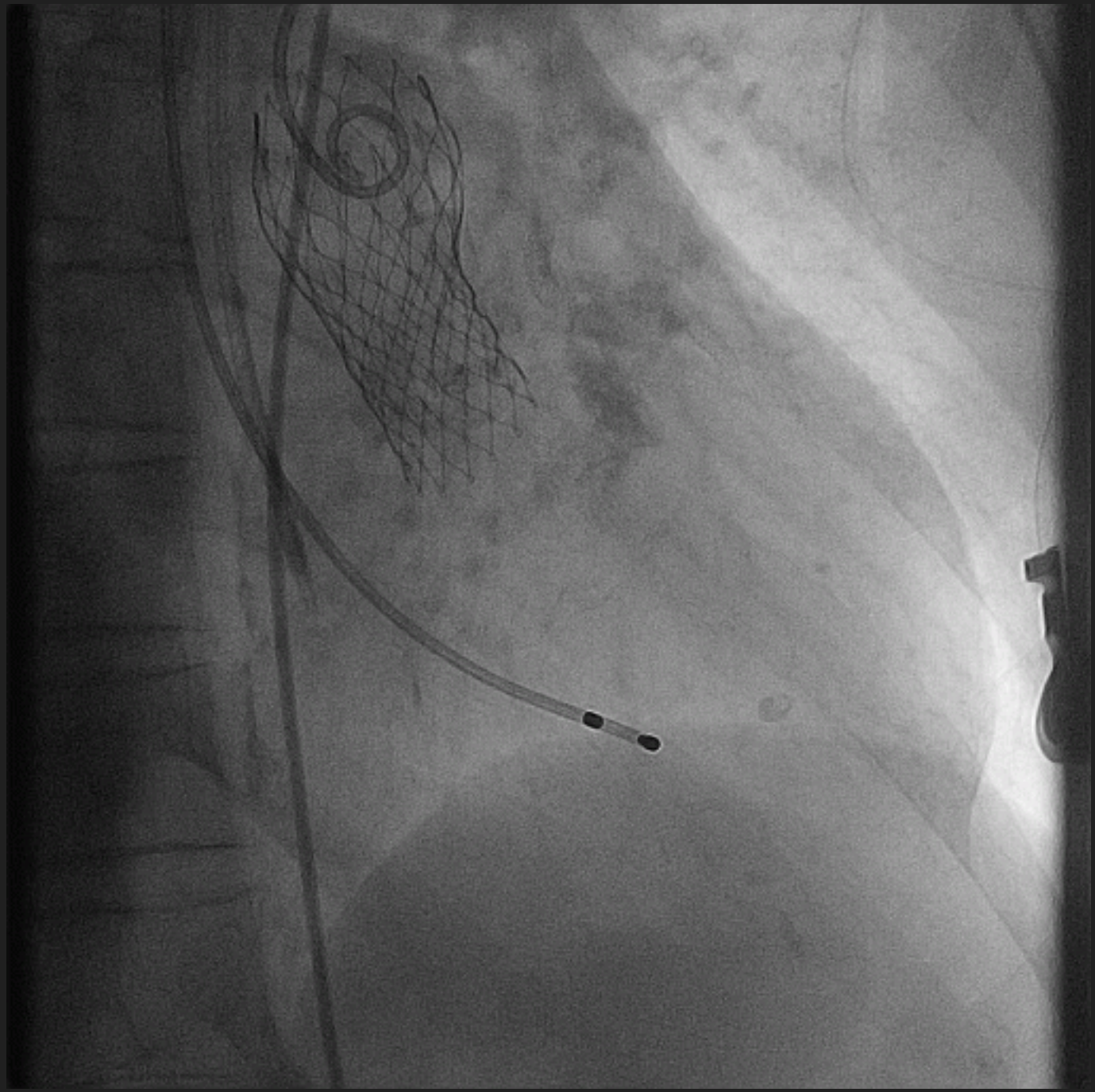


Transfemoral Core Valve

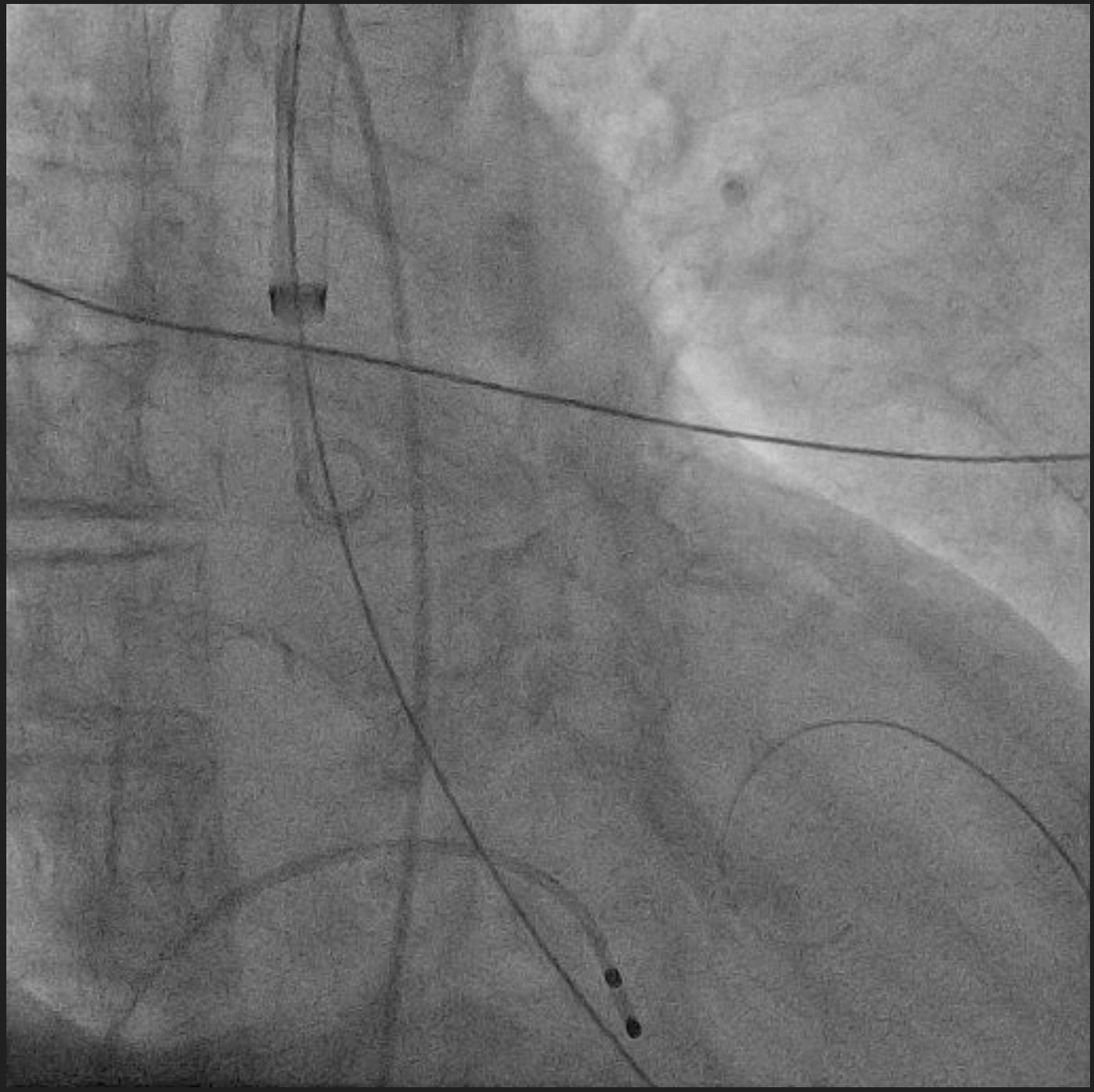


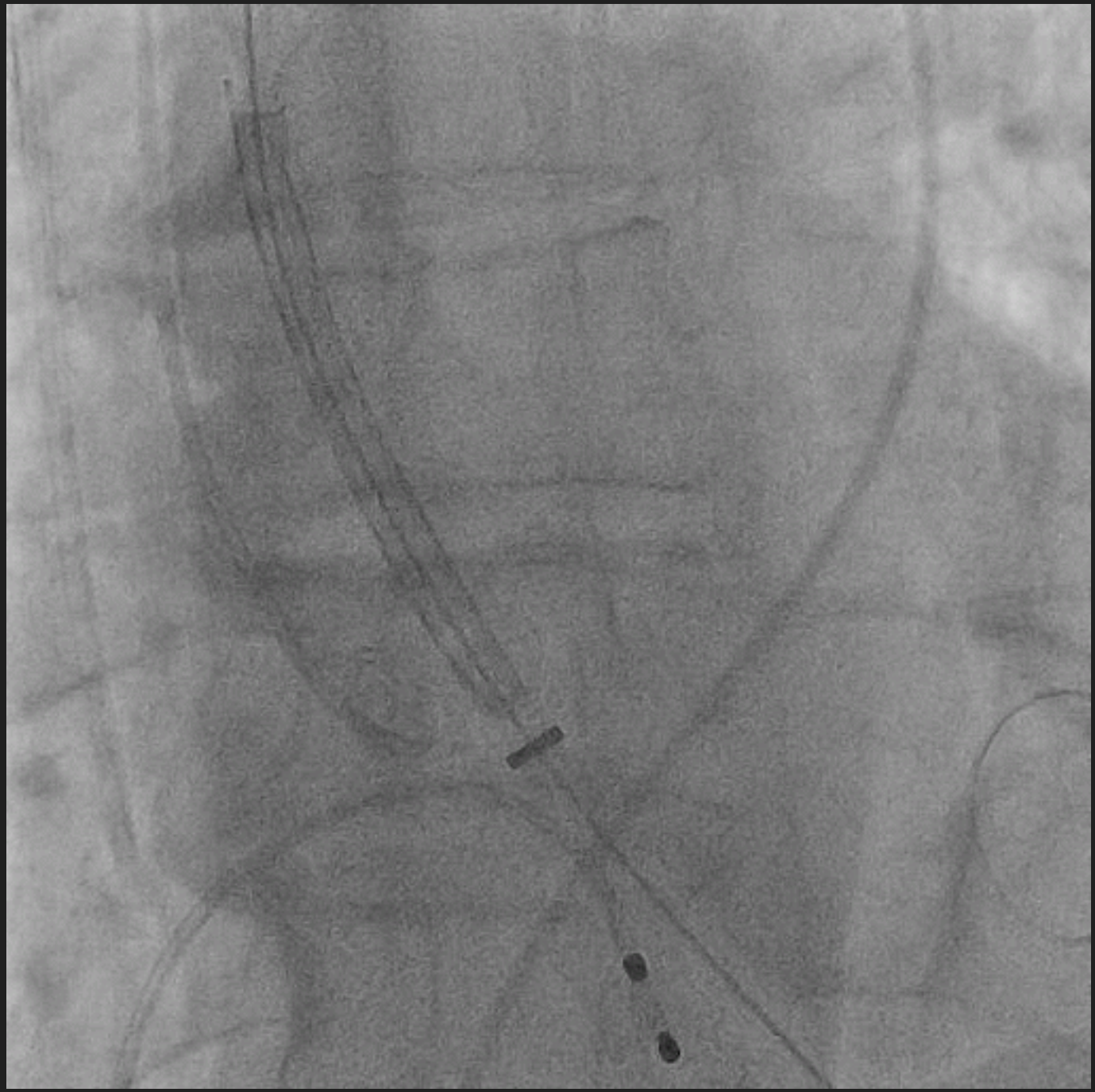


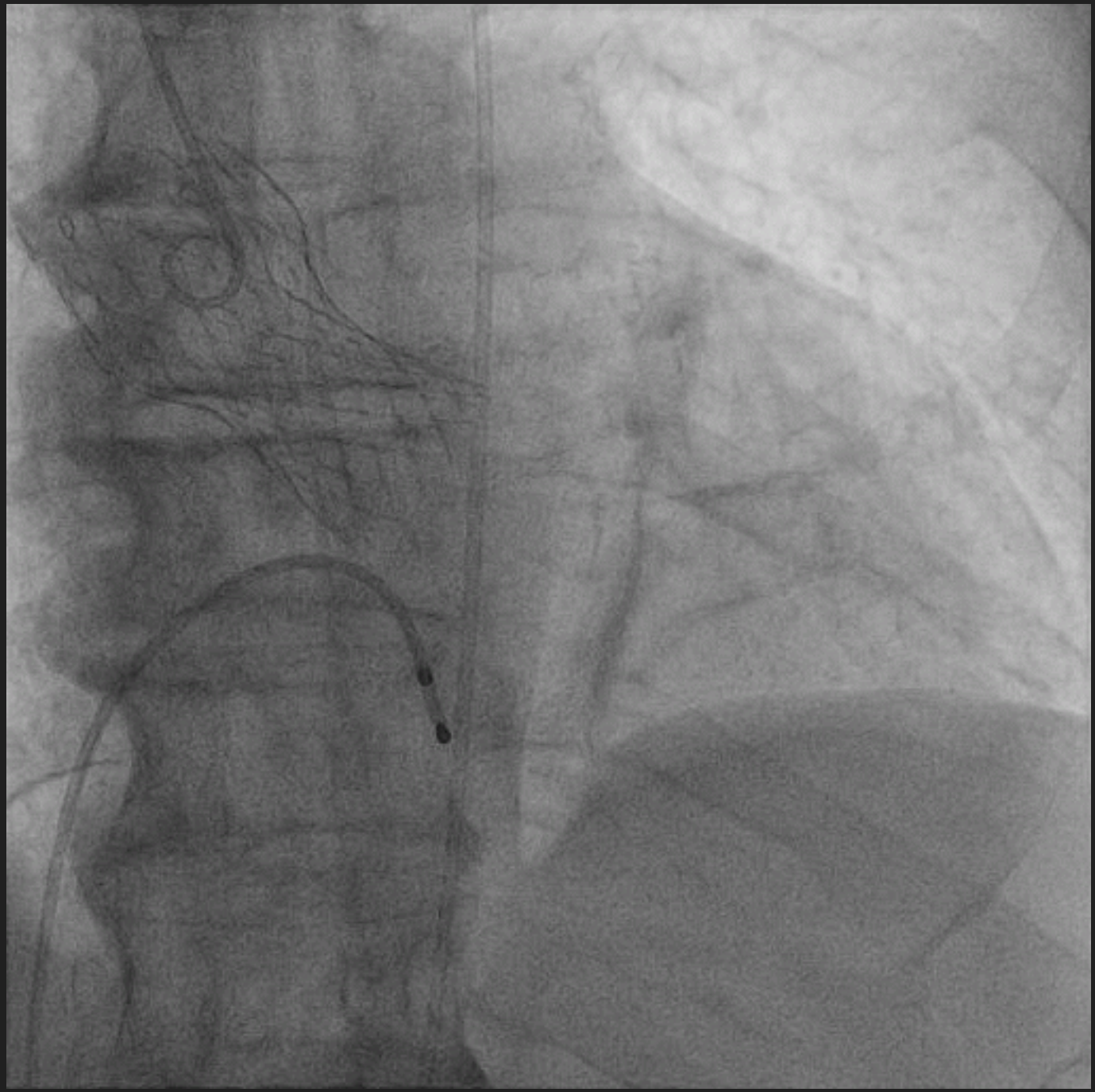


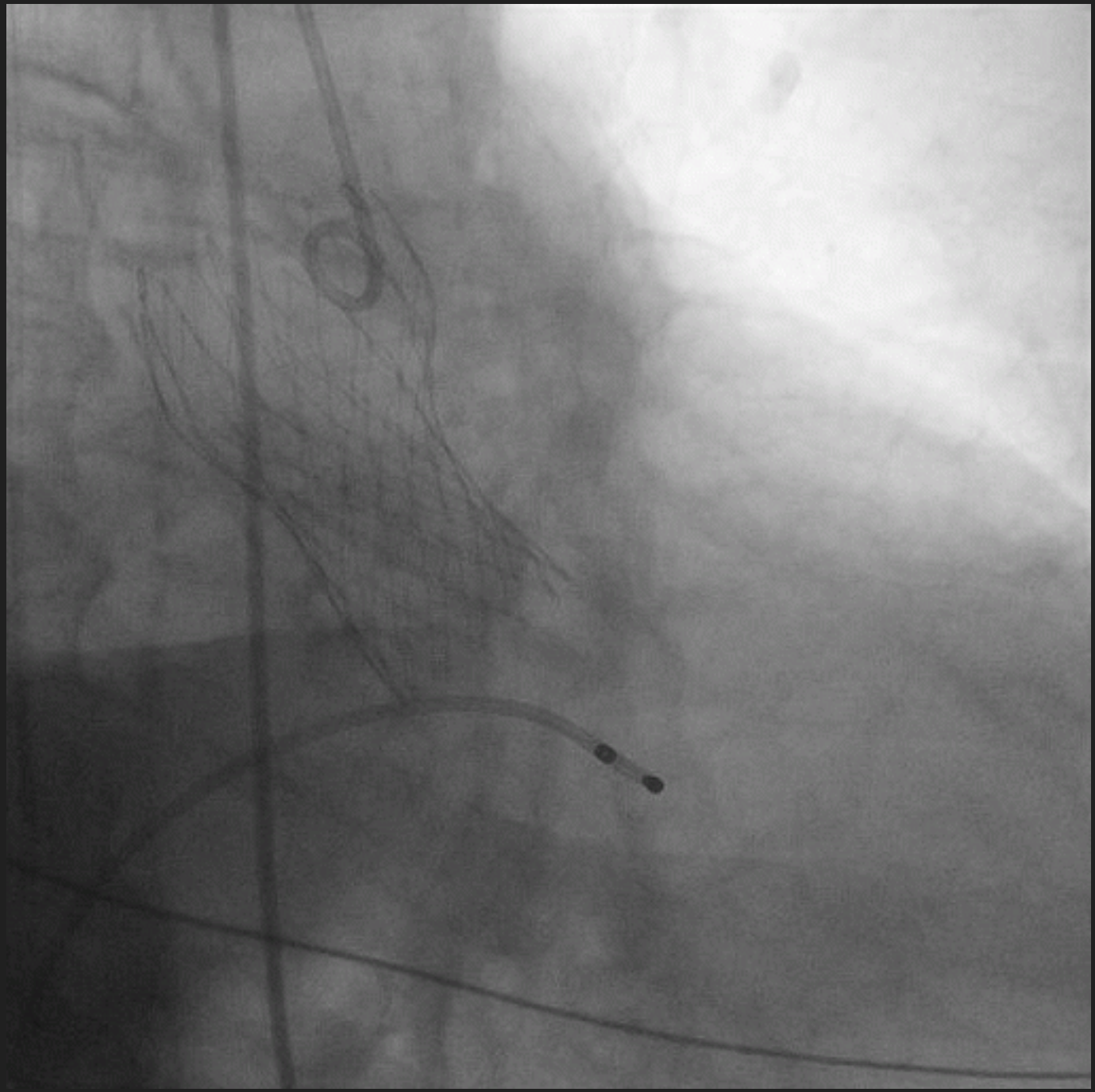


Transubclavian Core Valve

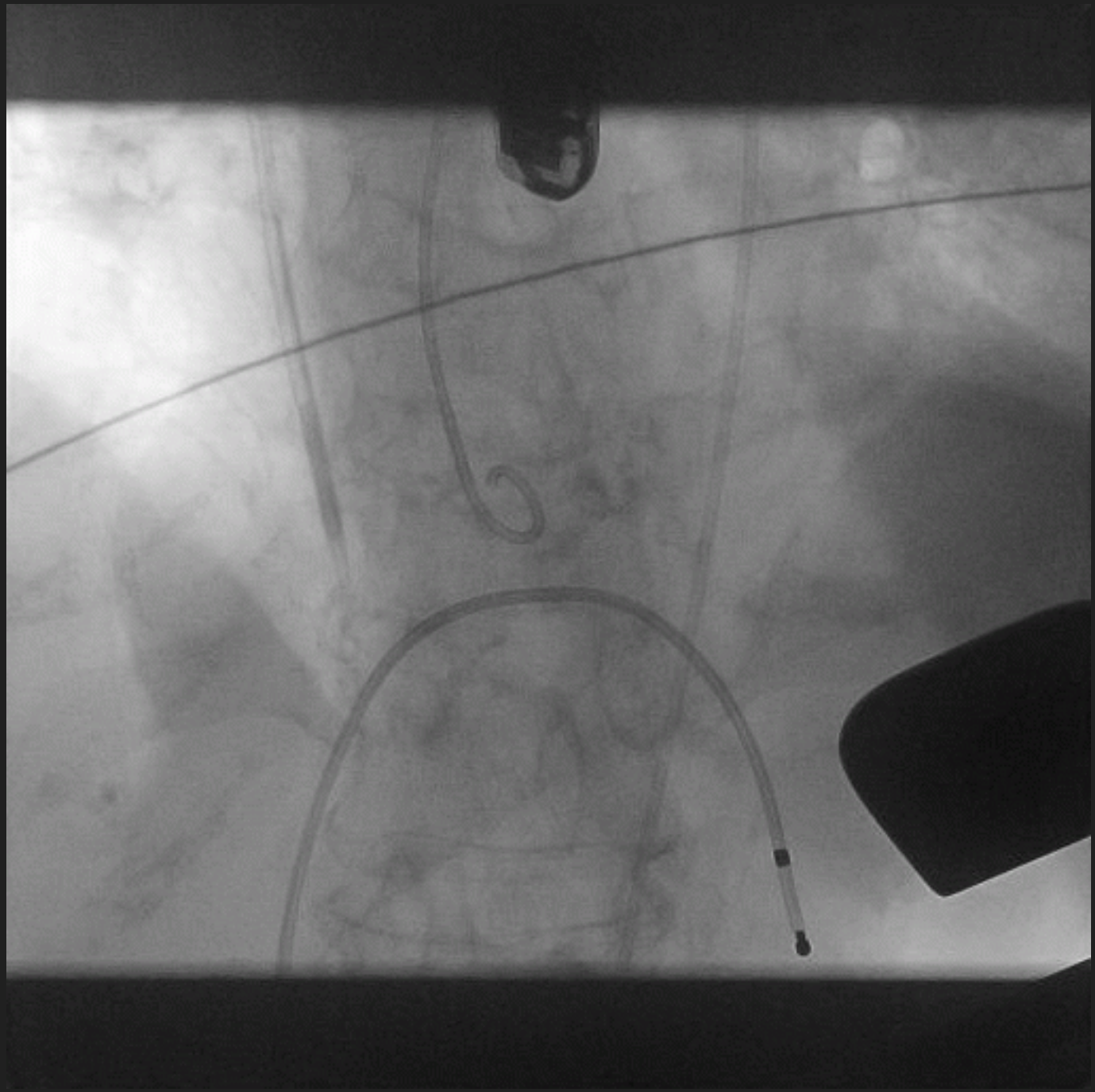


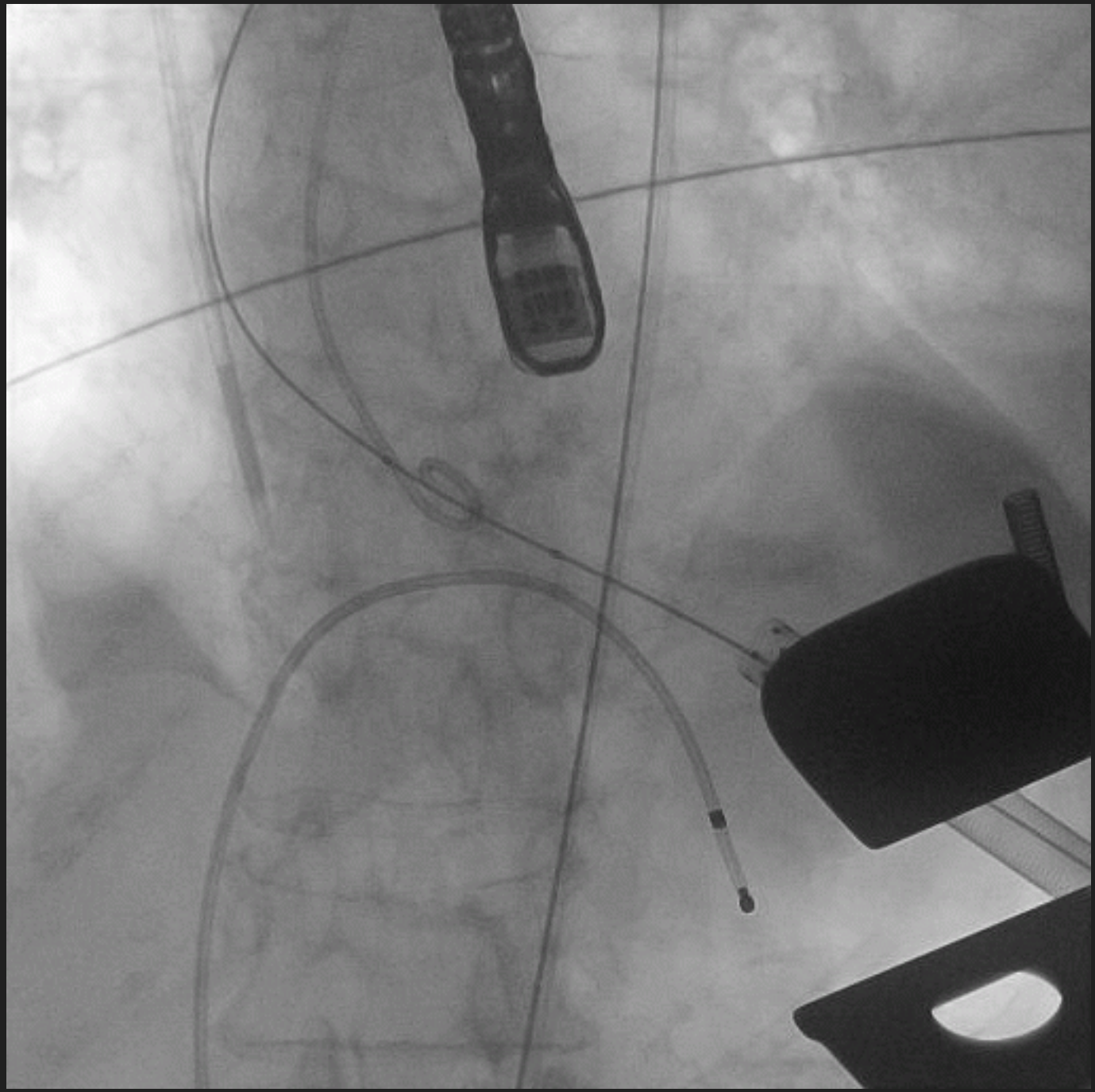


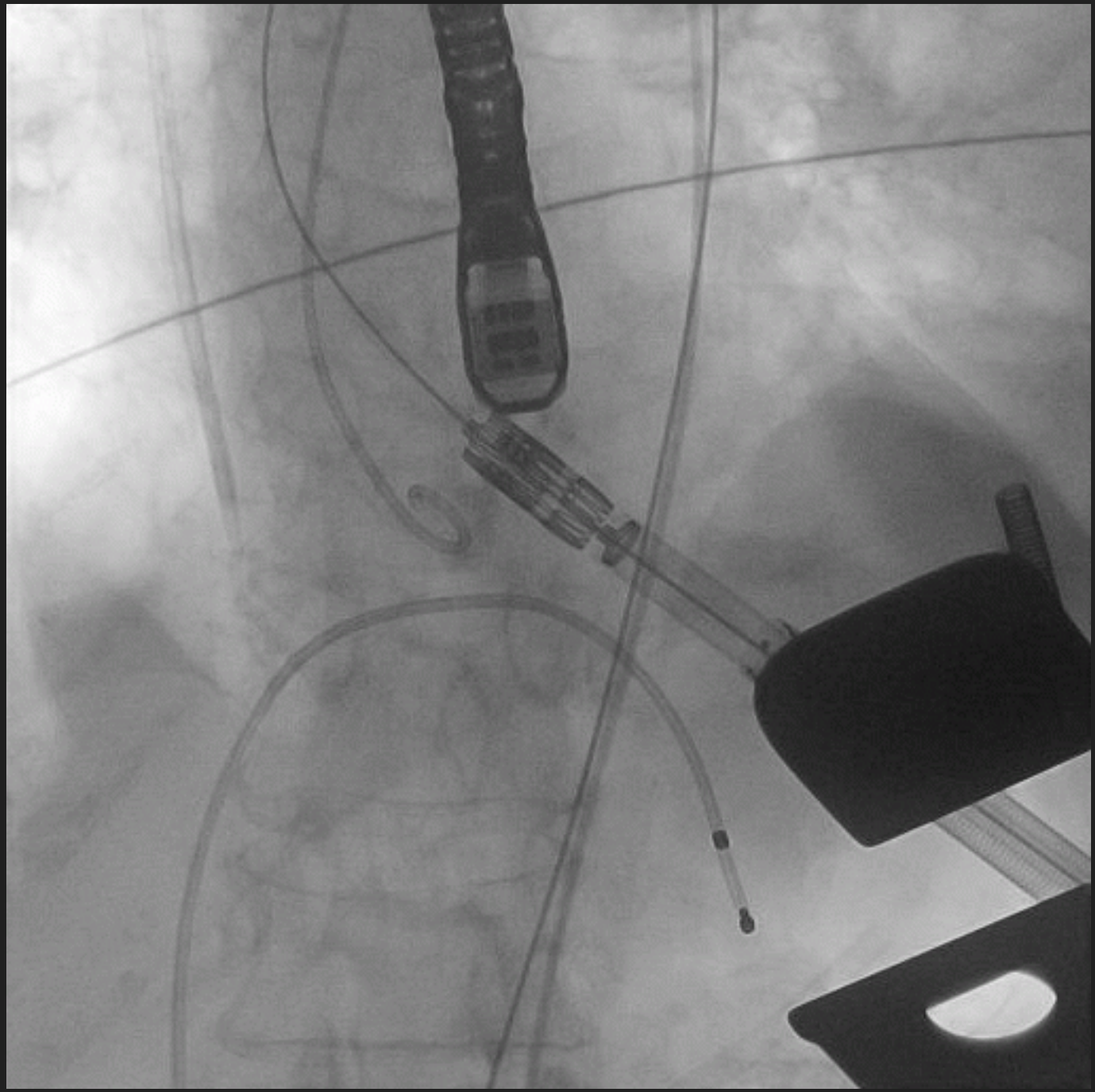


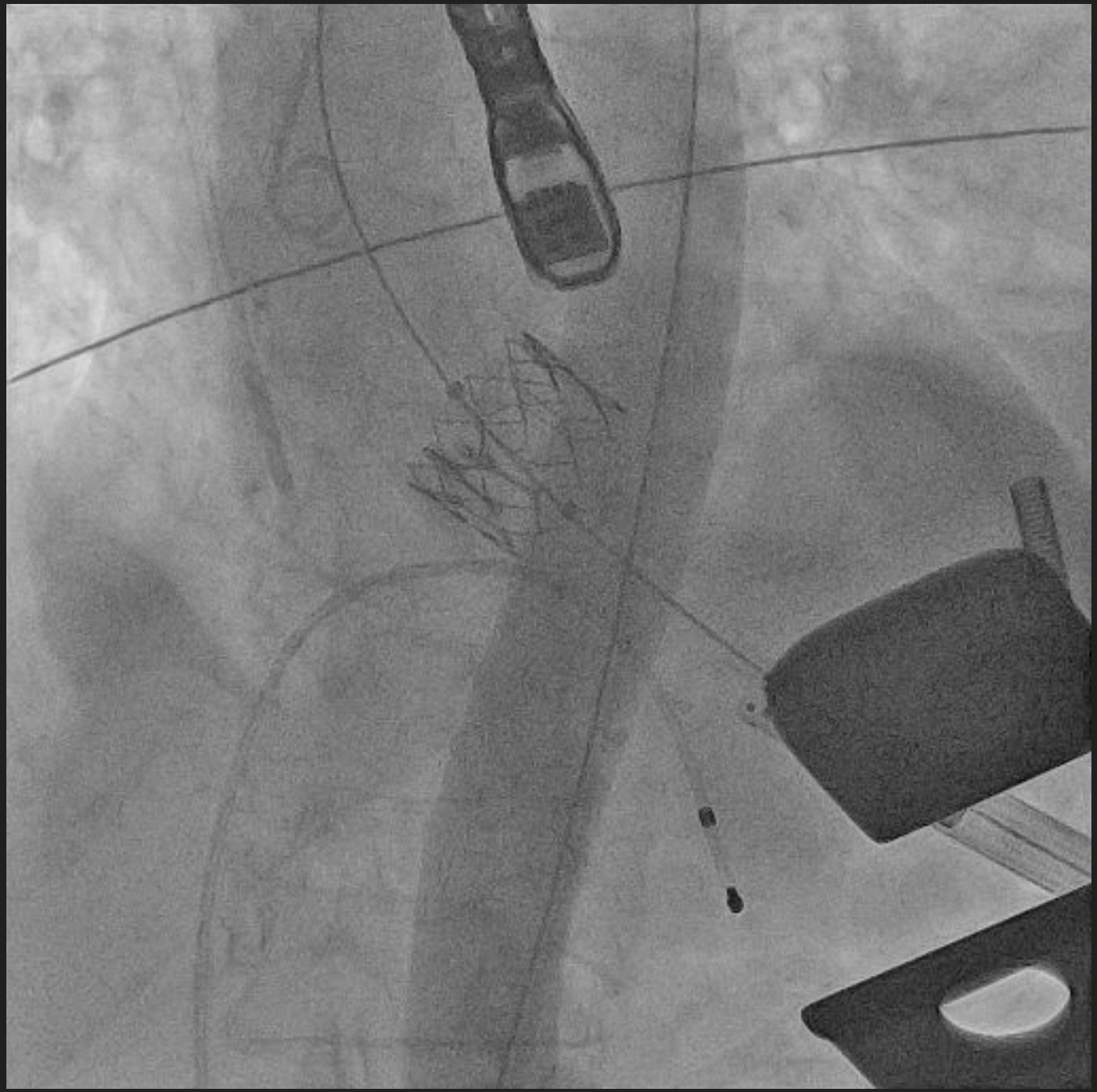


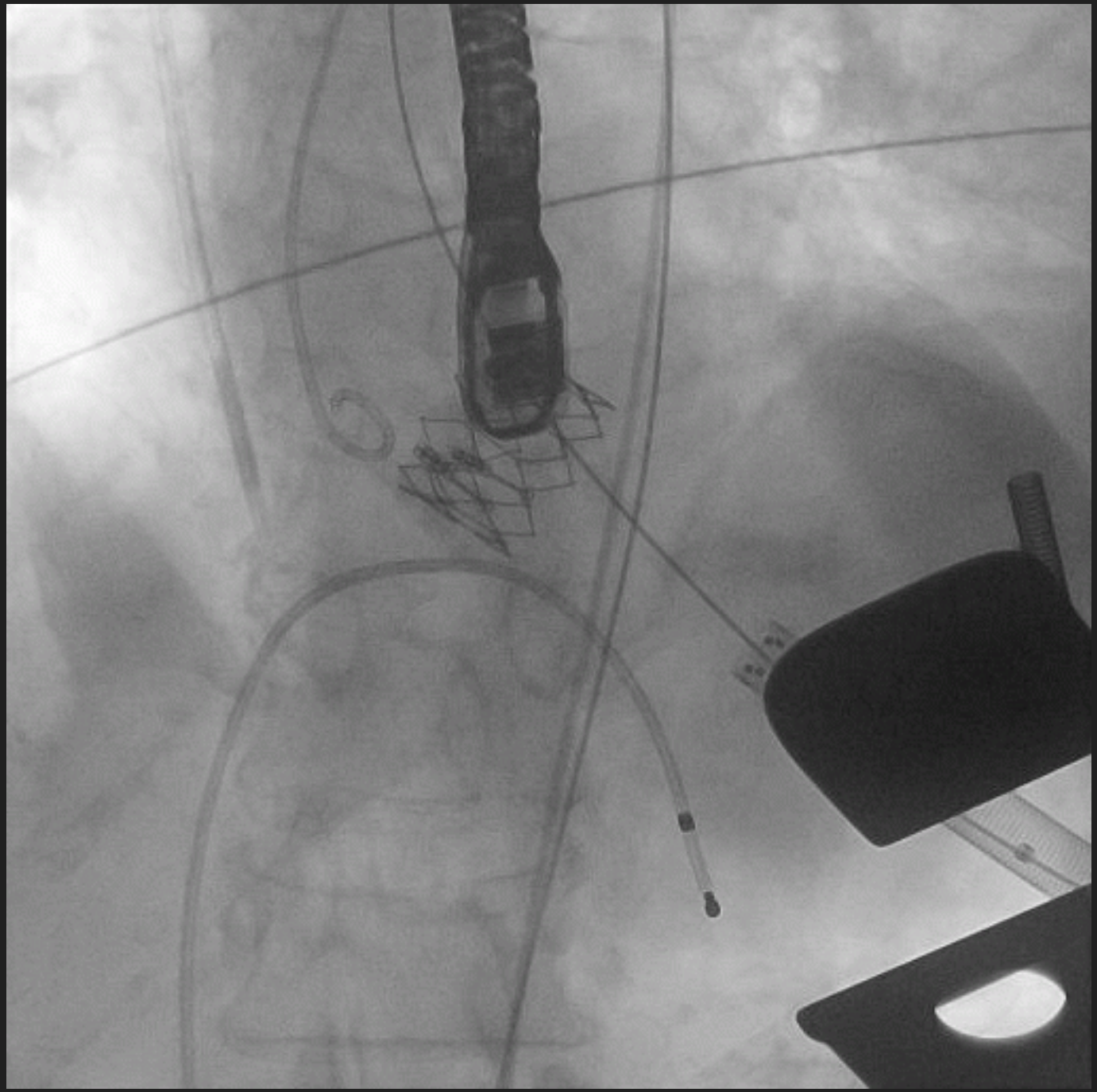
Transapical Edwards



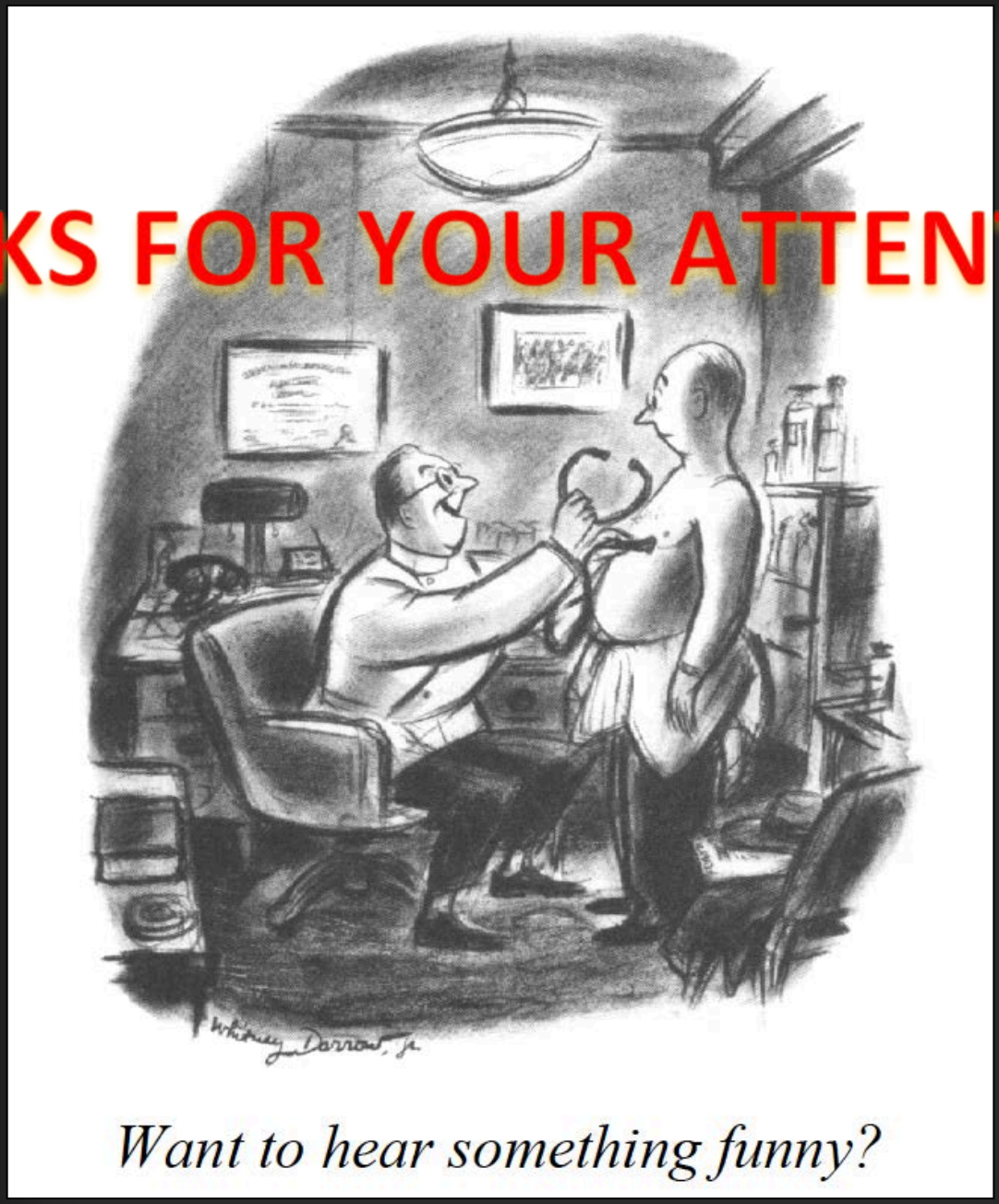








THANKS FOR YOUR ATTENTION



Want to hear something funny?