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Emoclinic Symposium - Sulle sponde del Ticino

"FOCUS IN CARDIONCOLOGIA E IMPLICAZIONI MEDICO-LEGALI NELL'EMERGENZA-URGENZA""

5-6 Maggio 2016

Hotel Dino - Baveno

Complicanza vascolare TAVI transfemorale: come correggerla?

Reale Maurizio

Emodinamica ASO Alessandria

Table 7 **Vascular access site and access-related complications**

Major vascular complications
Any aortic dissection, aortic rupture, annulus rupture, left ventricle perforation, or new apical aneurysm/pseudo-aneurysm OR
Access site or access-related vascular injury (dissection, stenosis, perforation, rupture, arterio-venous fistula, pseudoaneurysm, haematoma, irreversible nerve injury, compartment syndrome, percutaneous closure device failure) *leading to* death, life-threatening or major bleeding[a], visceral ischaemia, or neurological impairment OR
Distal embolization (non-cerebral) from a vascular source requiring surgery or resulting in amputation or irreversible end-organ damage OR
The use of unplanned endovascular or surgical intervention *associated* with death, major bleeding, visceral ischaemia or neurological impairment OR
Any new ipsilateral lower extremity ischaemia documented by patient symptoms, physical exam, and/or decreased or absent blood flow on lower extremity angiogram OR
Surgery for access site-related nerve injury OR
Permanent access site-related nerve injury OR
Minor vascular complications
Access site or access-related vascular injury (dissection, stenosis, perforation, rupture, arterio-venous fistula, pseudoaneuysms, haematomas, percutaneous closure device failure) *not leading to* death, life-threatening or major bleeding[a], visceral ischaemia, or neurological impairment OR
Distal embolization treated with embolectomy and/or thrombectomy and not resulting in amputation or irreversible end-organ damage OR
Any unplanned endovascular stenting or unplanned surgical intervention not meeting the criteria for a major vascular complication OR
Vascular repair or the need for vascular repair (via surgery, ultrasound-guided compression, transcatheter embolization, or stent-graft) OR
Percutaneous closure device failure
Failure of a closure device to achieve haemostasis at the arteriotomy site leading to alternative treatment (other than manual compression or adjunctive endovascular ballooning)

[a]Refers to VARC bleeding definitions.

Vascular complications

EUROPEAN SOCIETY OF CARDIOLOGY®

European Heart Journal (2012) **33**, 2403–2418
doi:10.1093/eurheartj/ehs255

FASTTRACK CLINICAL

Updated standardized endpoint definitions for transcatheter aortic valve implantation: the Valve Academic Research Consortium-2 consensus document†

TAVI approaches

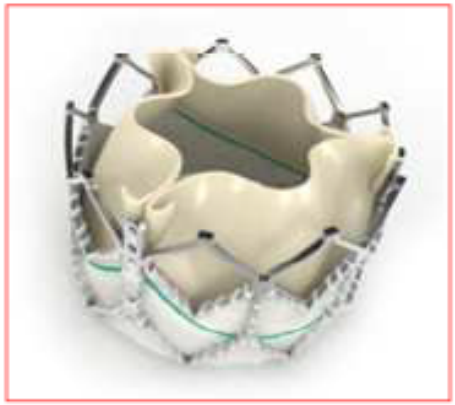
Carotid approach

Right subclavian artery

Left Subclavian artery
December 2010 CE mark

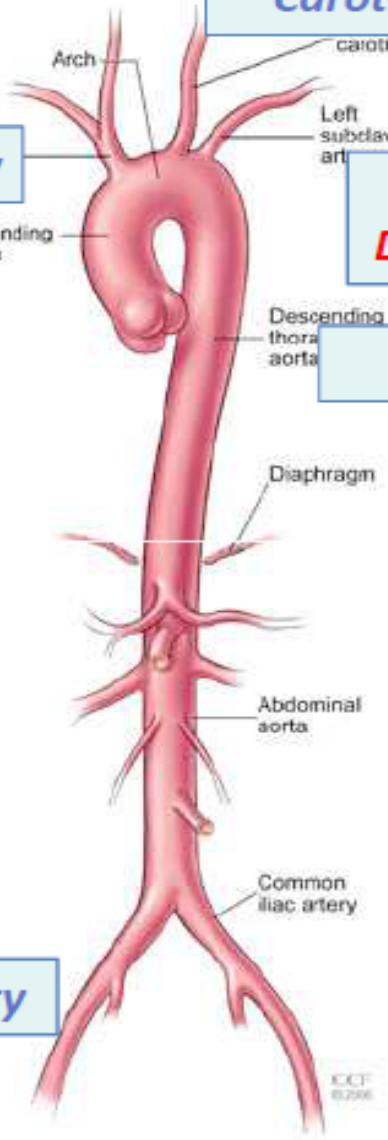
Transaortic access

Transapical approach



Right transfemoral artery

Left transfemoral artery



Complicanze vascolari

- Asse iliaco-femorale
- Fallimento device percutanei di chiusura
- Dissezione aortica-rottura aortica
- Rottura anulus

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Table 1. Vascular Access and Complication Rate in Larger Series (≥100 Patients) of Predominantly Transfemoral Transcatheter Aortic Valve Implantation

First Author (Year)	N	Sheath Size, F	Technique	Vascular Complication Rate, %*	VARC Definition
Piazza et al. (2008)	646	18–21	Percutaneous, ProStar†	1.9	No
Bleiziffer et al. (2009)	137	18–24	Mostly percutaneous, ProStar†	11.7	No
Webb et al. (2009)	113	22–24	Mostly surgical cutdown	8.0	No
Leon et al. (2010)	179	22–24	Surgical cutdown	16.2	Yes
Tamburino et al. (2011)	679	18–24	Mostly percutaneous, ProStar†	2.0	No
Smith et al. (2011)	348	22–24	Surgical cutdown	11.0	Yes
Gurvitch et al. (2011)	310	18–24	Mostly percutaneous, ProGlide†	11.7	Yes
Lange et al. (2011)	412	18–24	Mostly percutaneous, ProStar†	10.2	No
Hayashida et al. (2011)	130	18–24	Mostly percutaneous, ProStar†	17.3	Yes
Stähli et al. (2011)	130	18–24	Mostly percutaneous	11.5	Yes
Nuis et al. (2011)	165	18	Mostly percutaneous	15.0	Yes
Moat et al. (2011)	599	22–24	Not reported	8.4	No
Toggweiler et al. (2012)	137	18–24	Percutaneous, ProGlide†	5.6	Yes
Gilard et al. (2012)	2361	18–24	Not reported	5.5	Yes

*Major vascular complication rate reported in series that used VARC definitions. †ProStar and ProGlide closure systems, Abbott Vascular, Abbott Park, Illinois.

30-Day & 1 Year Outcomes (2)

Outcome	30 Days			1 Year		
	TAVI (N=179)	Standard Therapy (N=179)	P Value†	TAVI (N=179)	Standard Therapy (N=179)	P Value†
	no. of patients (%)			*no. of patients (%)*		
Vascular complications						
All	55 (30.7)	9 (5.0)	<0.001	58 (32.4)	13 (7.3)	<0.001
Major	29 (16.2)	2 (1.1)	<0.001	30 (16.8)	4 (2.2)	<0.001
Acute kidney injury						
Creatinine >3 mg/dl (265 μmol/liter)¶	0	1 (0.6)	1.00	2 (1.1)	5 (2.8)	0.45
Renal-replacement therapy‖	2 (1.1)	3 (1.7)	1.00	3 (1.7)	6 (3.4)	0.50
Major bleeding	30 (16.8)	7 (3.9)	<0.001	40 (22.3)	20 (11.2)	0.007
Cardiac reintervention						
Balloon aortic valvuloplasty	1 (0.6)**	2 (1.1)	1.00	1 (0.6)	66 (36.9)††	<0.001
Repeat TAVI‡‡	3 (1.7)	NA	—	3 (1.7)	NA	—
Aortic-valve replacement	0	3 (1.7)	0.25	2 (1.1)**	17 (9.5)	<0.001
Endocarditis	0	0	—	2 (1.1)	1 (0.6)	0.31
New atrial fibrillation	1 (0.6)	2 (1.1)	1.00	1 (0.6)	3 (1.7)	0.62
New pacemaker	6 (3.4)	9 (5.0)	0.60	8 (4.5)	14 (7.8)	0.27

Transcatheter Aortic Valve Implantation for Aortic Stenosis in Patients Who Cannot Undergo Surgery.
Martin B. Leon et al. The New England Journal of Medicine. September 2010

Other Clinical Events

At 30 Days (As Treated Patients)

THE PARTNER II TRIAL

Events (%)	S3HR Overall (n=583)	S3HR TF (n=491)	S3HR TA/TAo (n=92)	S3i Overall (n=1076)	S3i TF (n=951)	S3i TA/TAo (n=125)
Major Vascular Comps.	5.0	5.3	3.3	5.6	5.9	3.2
Bleeding - Life Threatening	6.3	5.5	10.9	5.4	4.4	12.9
Annular Rupture	0.3	0.2	1.1	0.2	0.2	0
Myocardial Infarctions	0.5	0.4	1.1	0.3	0.3	0
Coronary Obstruction	0.2	0	1.1	0.4	0.4	0
Acute Kidney Injury	1.0	0.8	2.2	0.5	0.3	1.6
New Permanent Pacemaker	13.0	13.2	12.0	10.1	10.4	7.2
Aortic Valve Re-intervention	1.0	0.8	2.2	0.7	0.8	0
Endocarditis	0.2	0.2	0	0.1	0.1	0

Evolution of the Edwards TAVI Valves

Cribier-Edwards

2002

SAPIEN

2006

SAPIEN XT

2009

SAPIEN 3

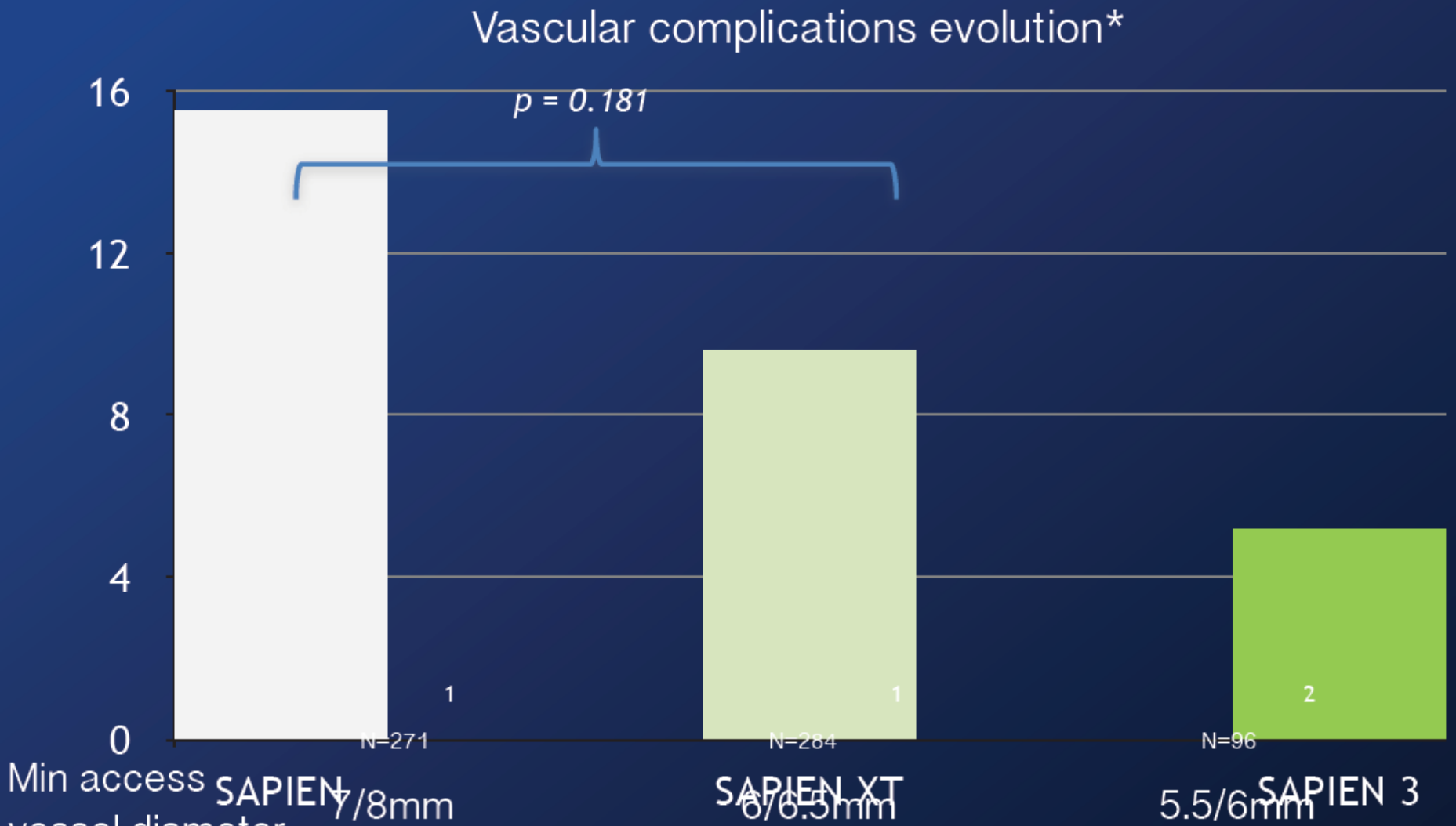
2013

Edwards Sapien 3

NovaFlex+

NovaFlex 4 (“Commander”)

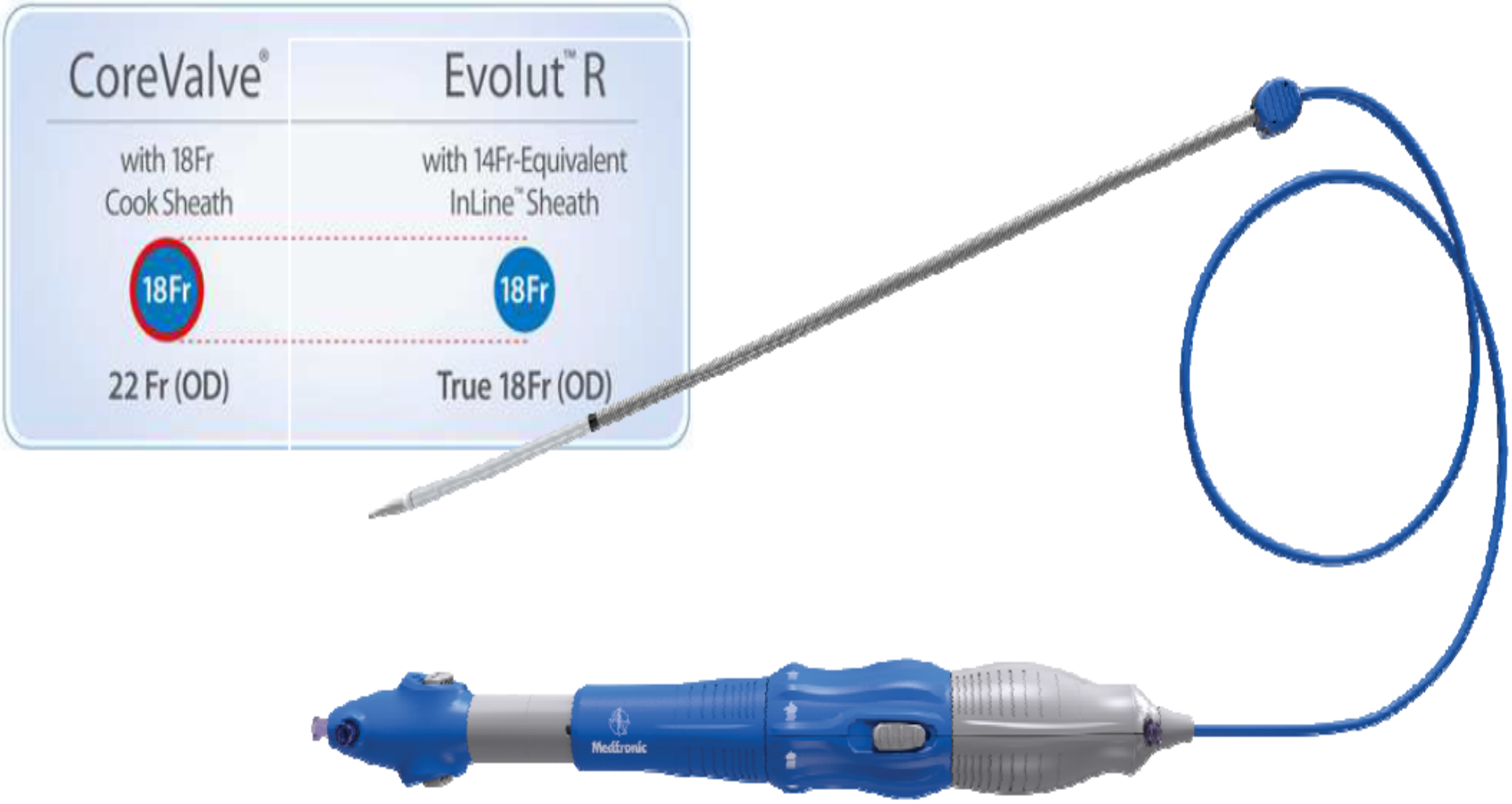
Reduction in sheath profile
Lower vascular complication rates



* Major vascular complications as defined by VARC 2

[1]M. Leon et al. A Randomized Evaluation of the SAPIEN XT Transcatheter Valve System in Patients with Aortic Stenosis Who Are Not Candidates for Surgery: PARTNER II, Inoperable Cohort. ACC 2013 | San Francisco | March 10, 2013. [2]J. Webb et al. 30-Day Outcomes From the SAPIEN 3 CE mark trial PCR Paris | May 2014.

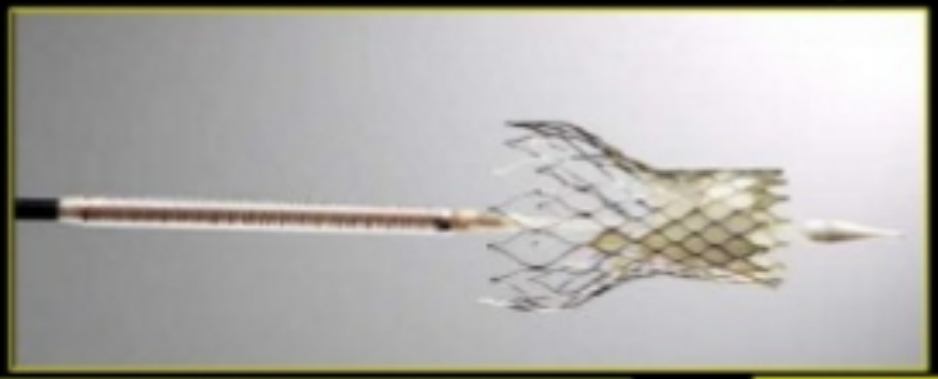
CoreValve Evolut R



Self expandable Medtronic CoreValve

Generation 1	Generation 2	Generation 3	Generation 4
25F	21F	18F	18F

2004-2005 → From 2006 → 2010



Porcine pericardium valve
Nitinol stent

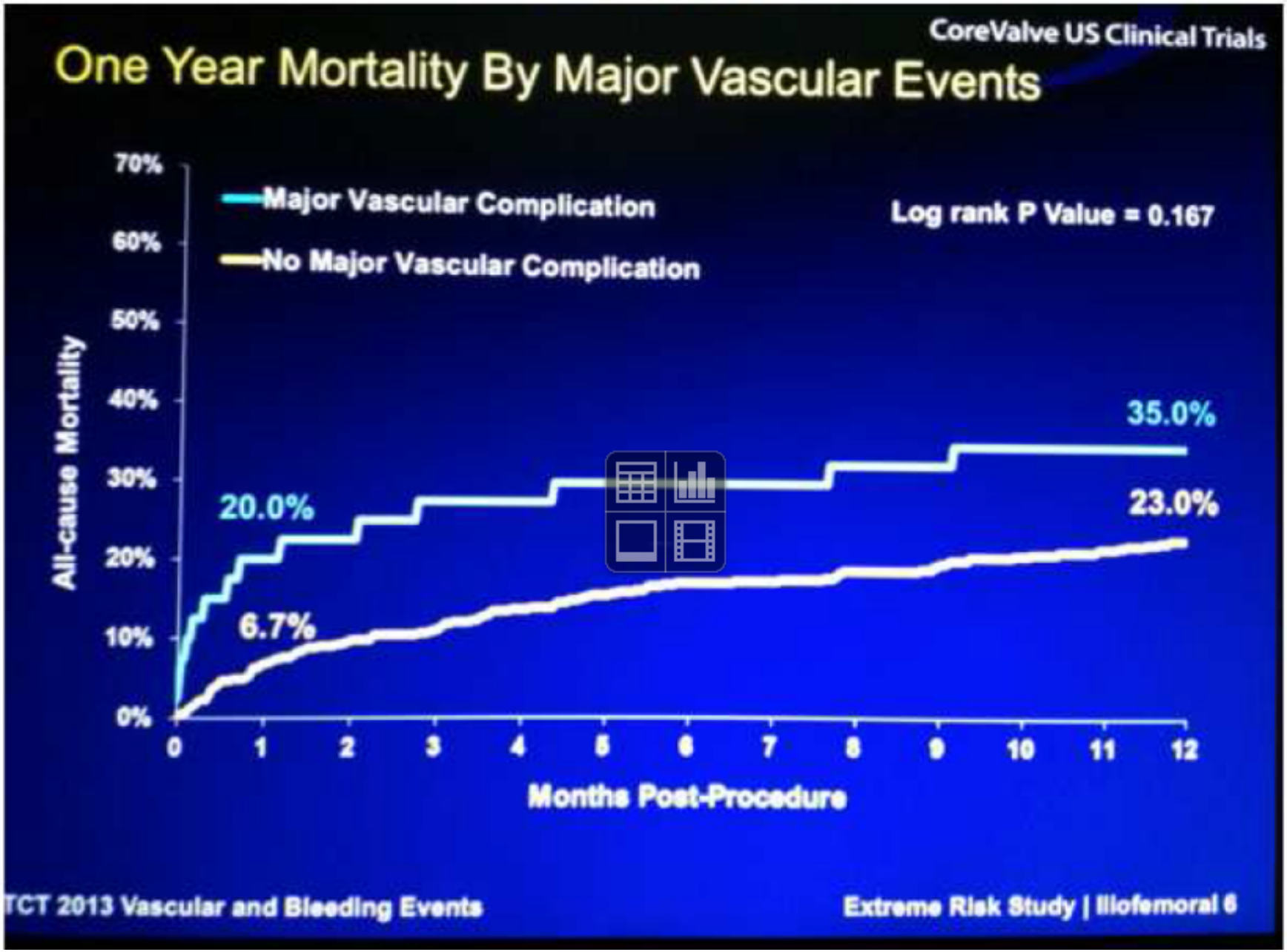
Improved delivery ?

Rilevanza clinica delle complicanze vascolari

- Impatto sulla mortalita'

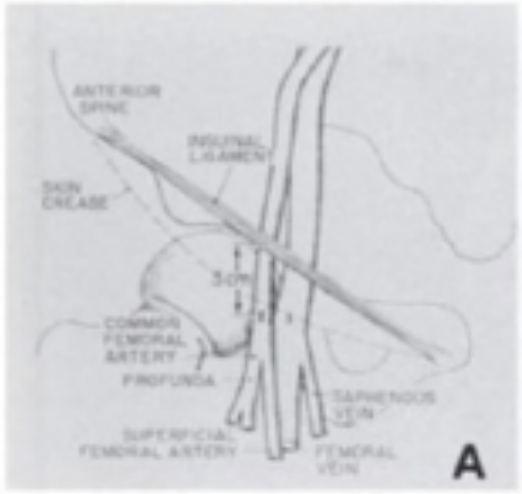
- Impatto sulla degenza ospedaliera
  - - maggiori 16 gg
  - - minori 11 gg
  - - nessuna 6 gg

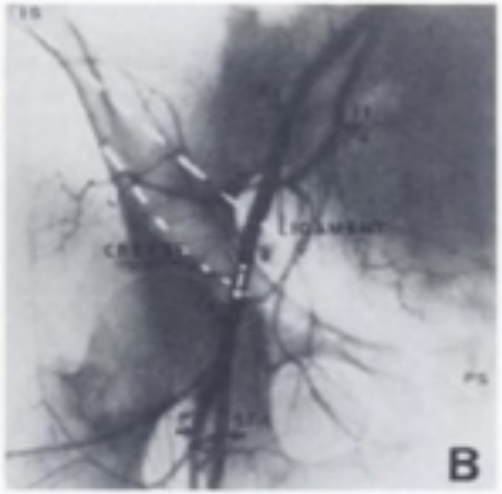
One Year Mortality By Major Vascular Events

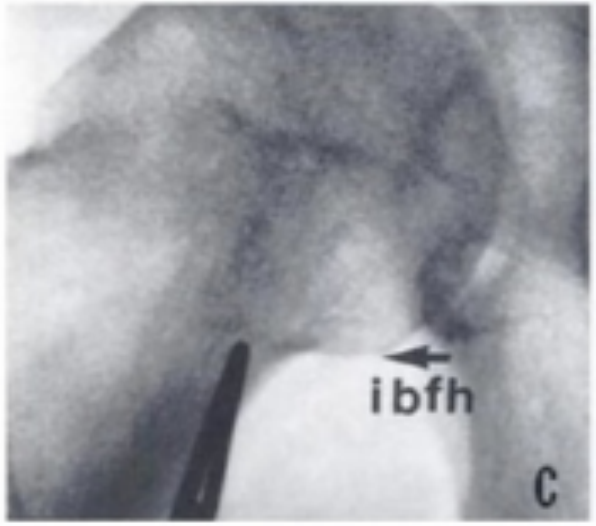


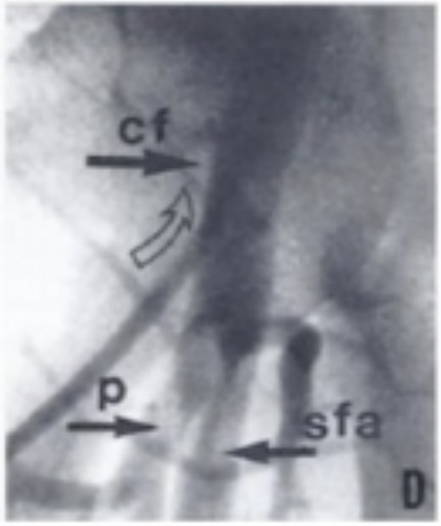
Ideal Insertion Site

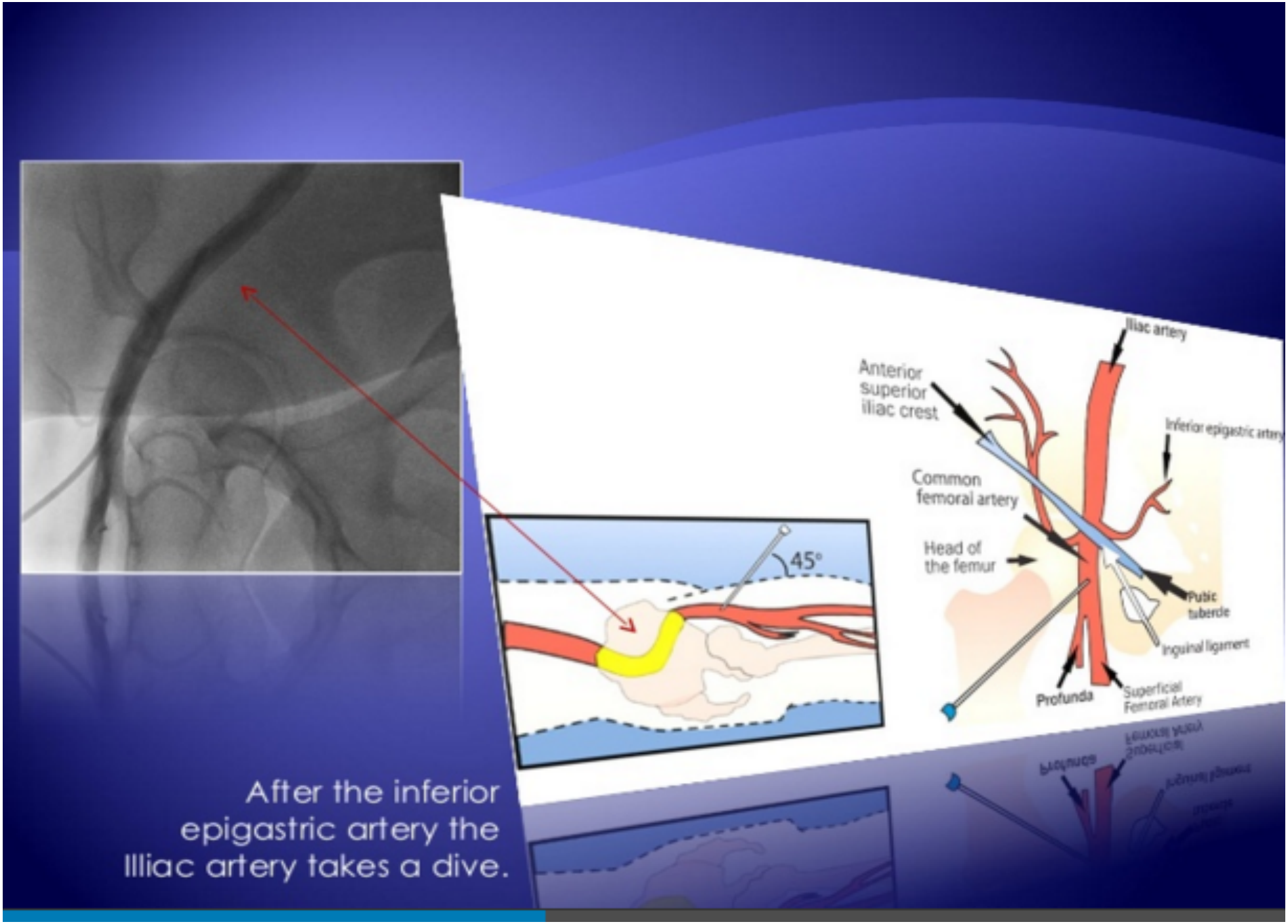
- Below inquinal ligament
- Above Common Femoral Artery (CFA) bifurcation

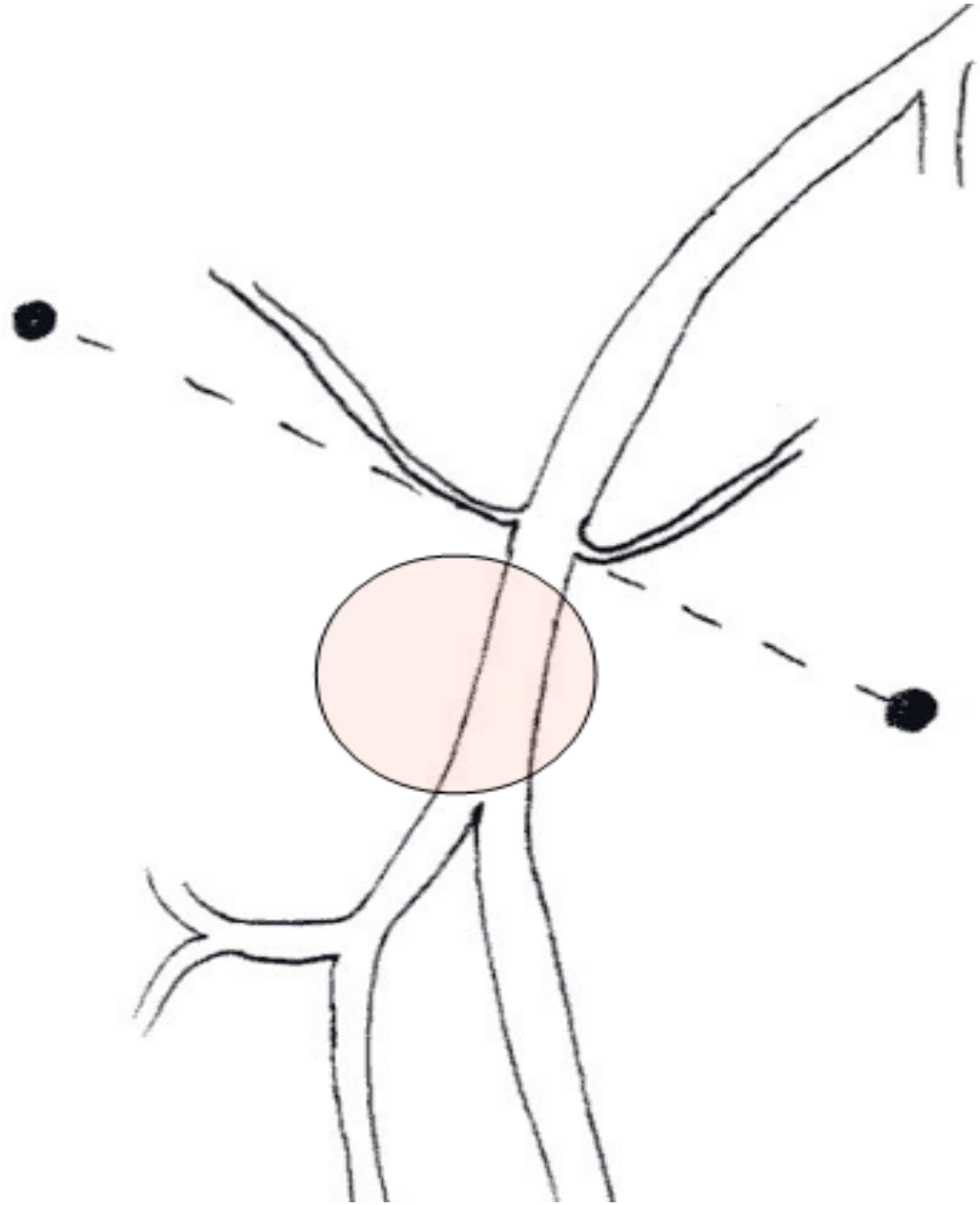









Iliac artery
Anterior superior iliac crest
Inferior epigastric artery
Common femoral artery
Head of the femur
45°
Pubic tuberde
Inguinal ligament
Profunda
Superficial Femoral Artery
After the inferior epigastric artery the Illiac artery takes a dive.



Fattori predittivi complicanze vascolari

- Piccole dimensioni dei vasi
- Calcificazioni moderate-severe
- Esperienza del centro

- La tortuosita' non è un fattore predittivo

Possibili complicanze iliaco-femorali

- Sanguinamenti
- Dissezione
- Rottura
- Stenosi-trombosi-occlusione
- Avulsione arteria
- Infezione sito accesso
- Fallimento chiusura percutanea (ematomi-pseudoaneurismi)

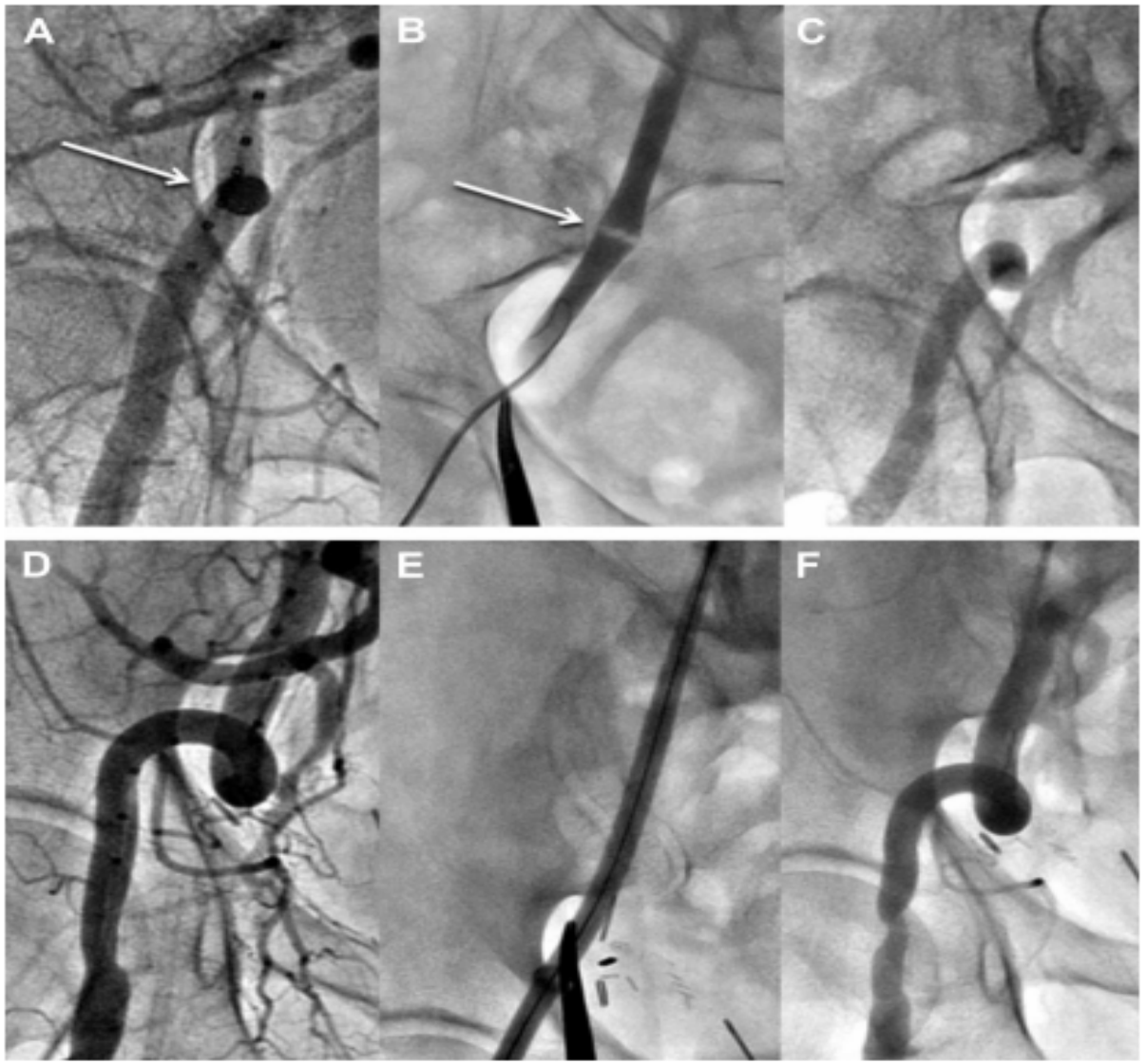
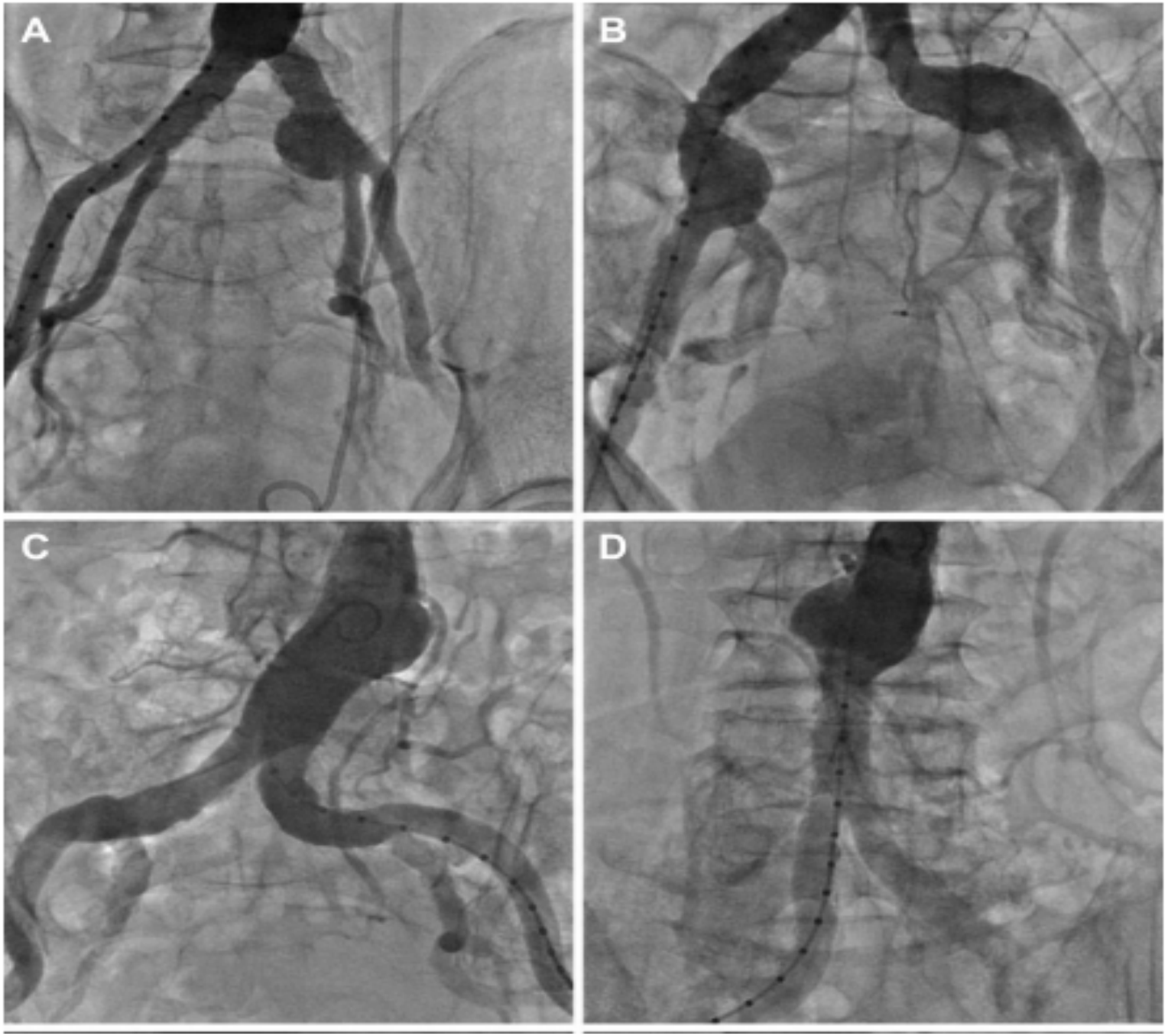
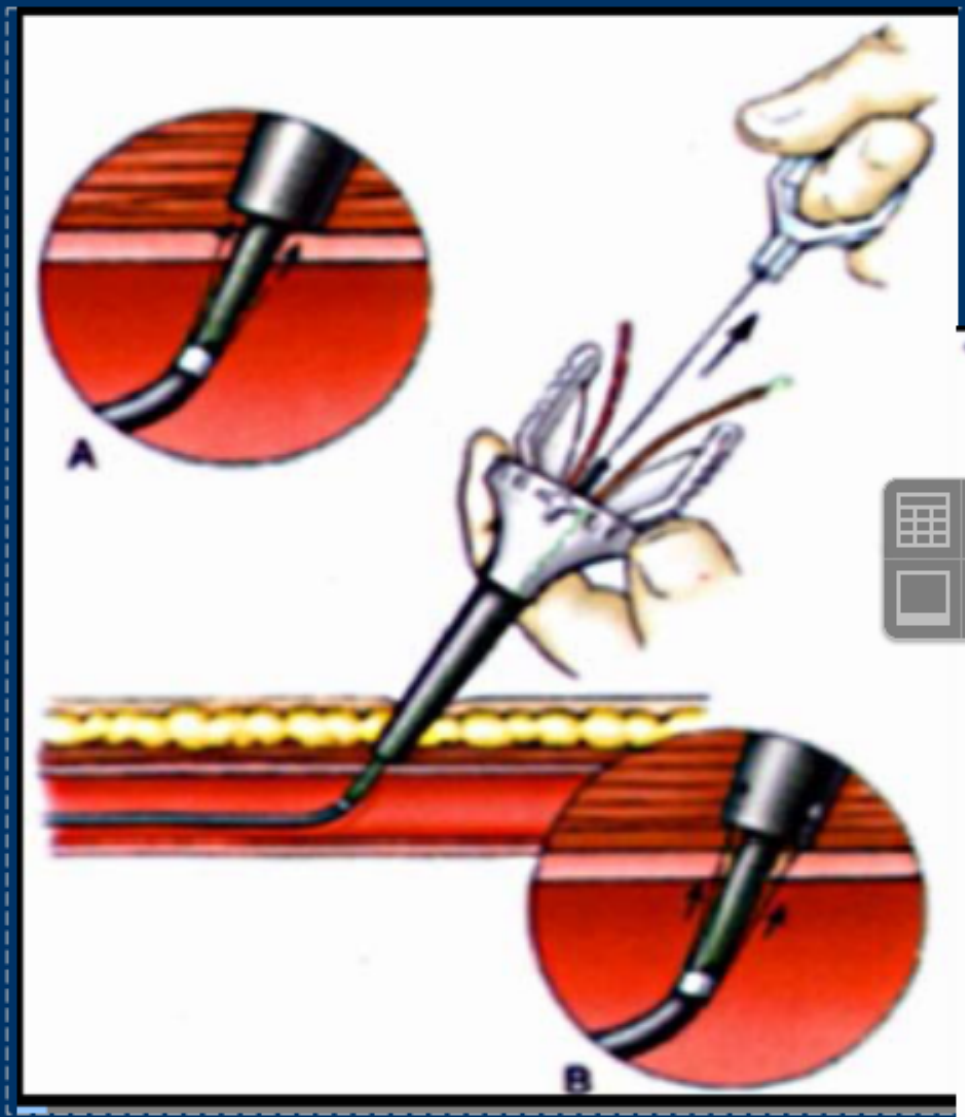


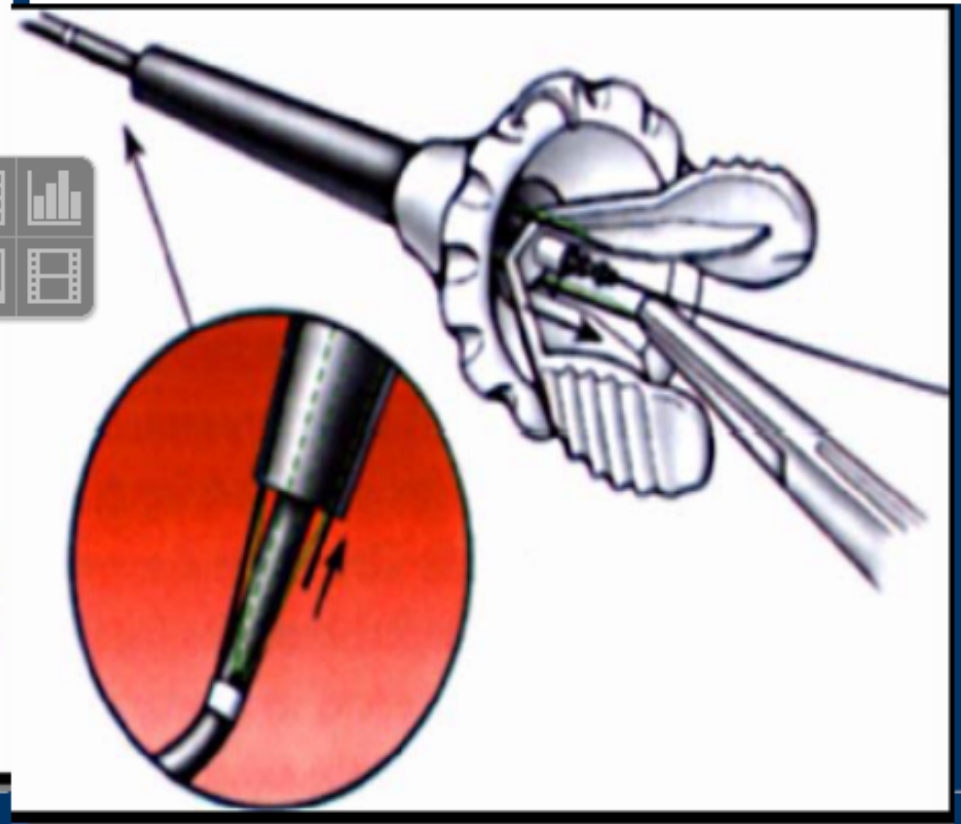
Figure 1. Transcatheter Aortic Valve Implantation in Patients With Iliofemoral Tortuosity

A patient with tortuosity of his external iliac artery **(A, arrow)** that straightened out after it was crossed with the wire and the sheath. However, the sheath kinked **(B, arrow)**, but the procedure was successfully carried out after the sheath was replaced. Contralateral angiography showed minimal stenosis after closure with ProGlide system (Abbott Vascular, Abbott Park, Illinois) **(C)**. Extensive tortuosity of the external iliac artery **(D)** that straightened out with an Amplatz Extra Stiff Wire (Cook Medical Inc., Bloomington, Indiana) and an 18-F Edwards sheath (Edwards Lifesciences, Irvine, California) **(E)**. Crossover angiography confirmed a good result after closure **(F)**.


A
B
C
D

PROSTAR XL
PROGLIDE





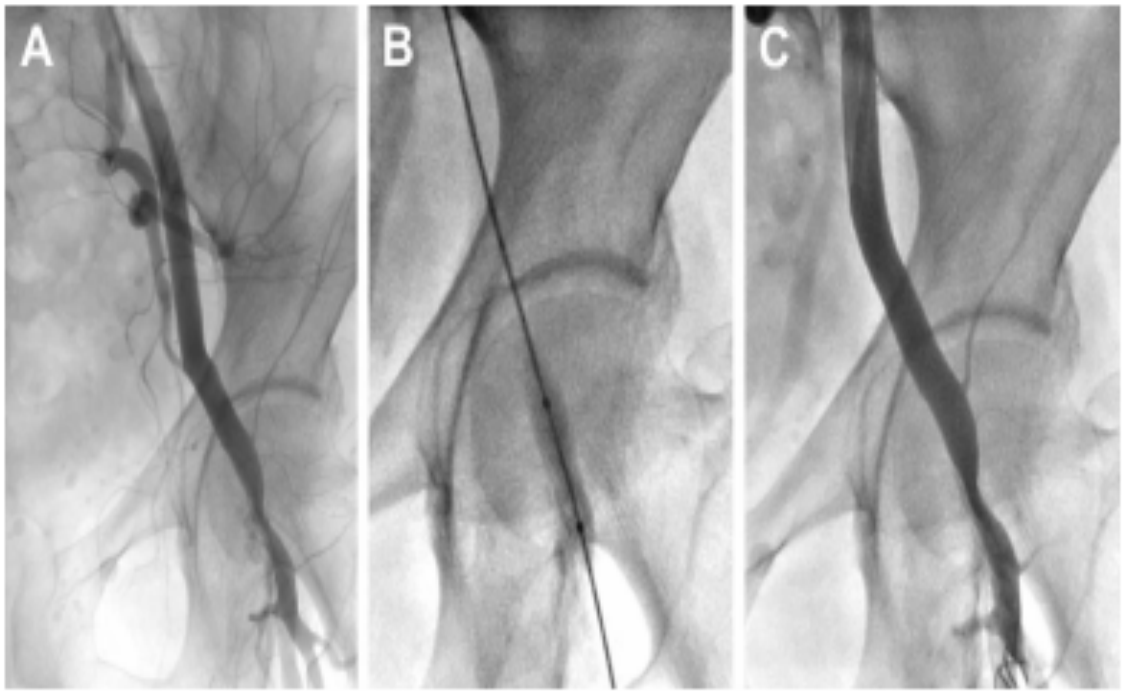


Figure 2. Treatment of Femoral Artery Injury With a Balloon Catheter

This patient presented with stenosis and ongoing bleeding of the common femoral artery after closure with the ProGlide system (Abbott Vascular, Abbott Park, Illinois) **(A)**. An 8 × 40-mm balloon was inflated **(B)**, resulting in hemostasis and moderate, asymptomatic residual stenosis **(C)**. This complication was managed without protamine reversal.

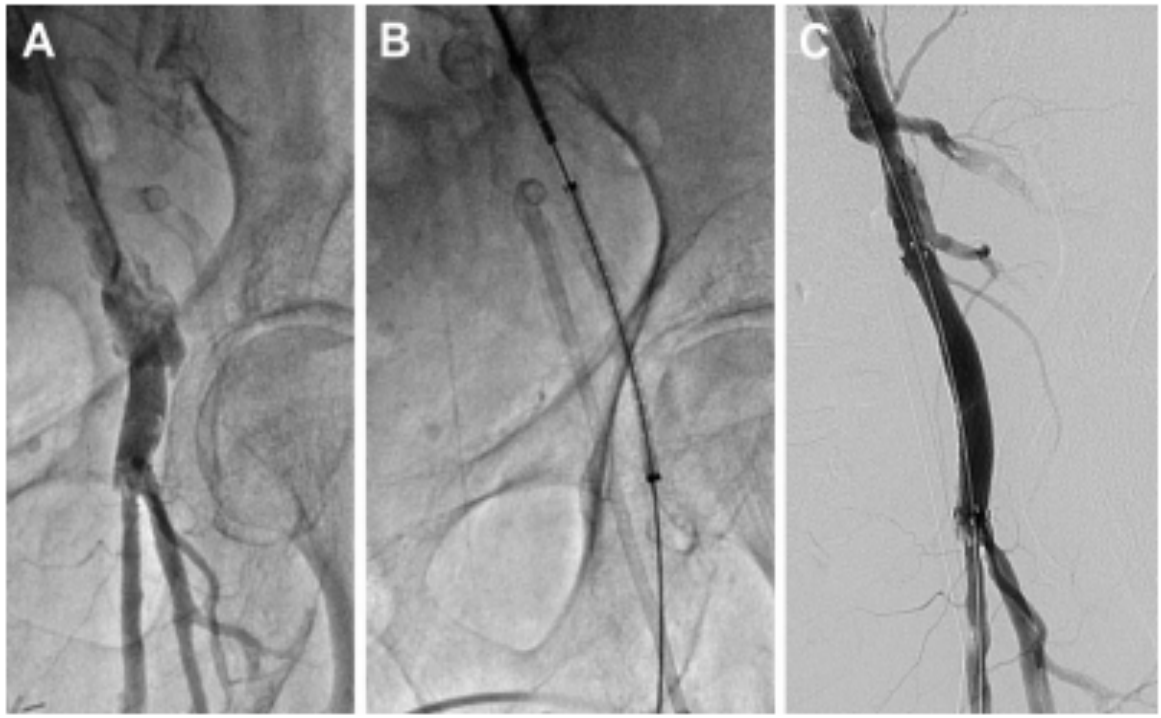


Figure 3. Treatment of Femoral Artery Injury With a Covered Stent

(A) This patient presented with acute hemorrhage of the femoral artery. Bleeding was controlled with balloon tamponade and then, a Fluency Plus 9 × 60-mm covered self-expanding stent-graft (Bard Canada Inc., Oakville, Ontario, Canada) was implanted with a good result **(B,C)**.

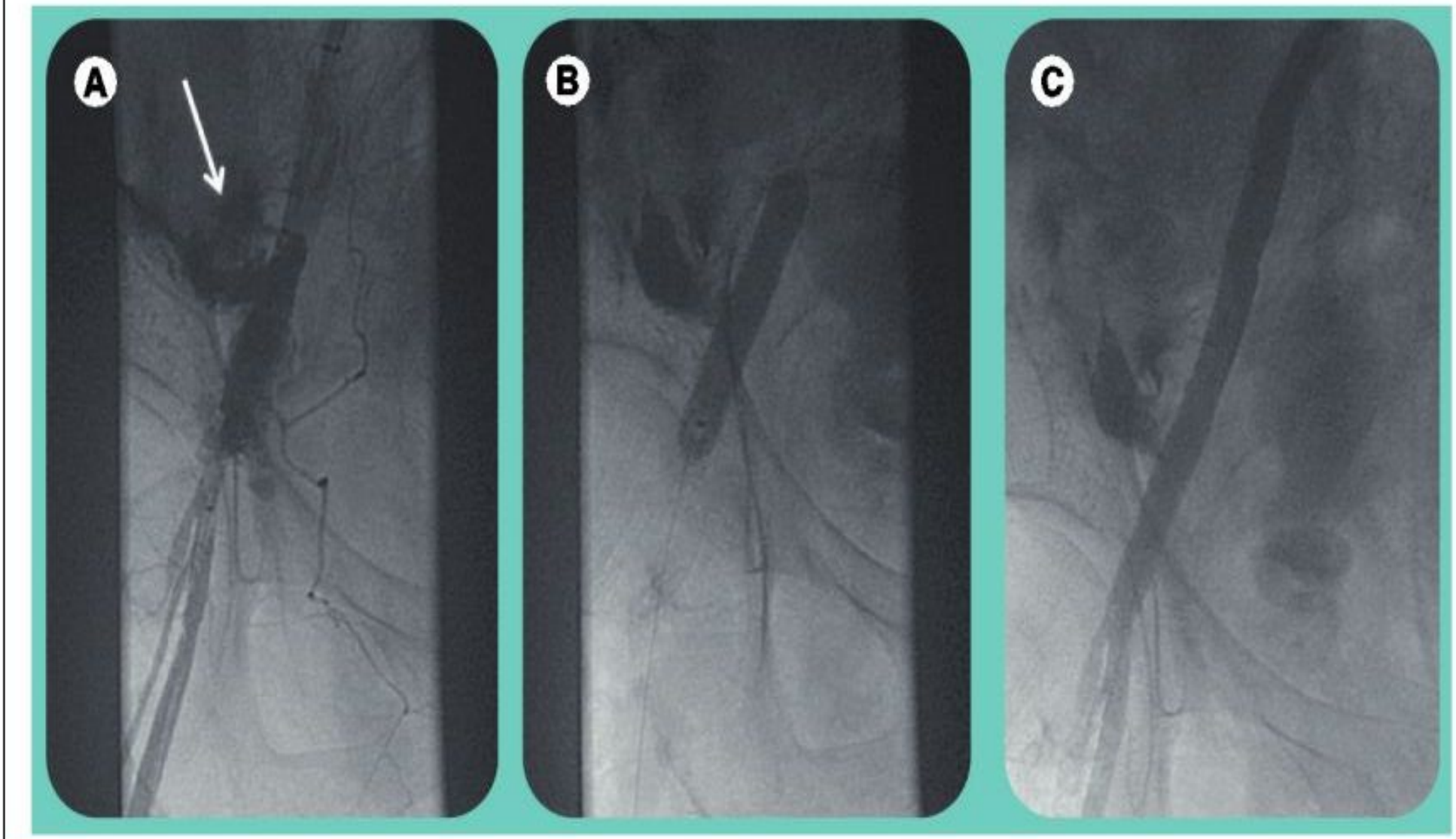
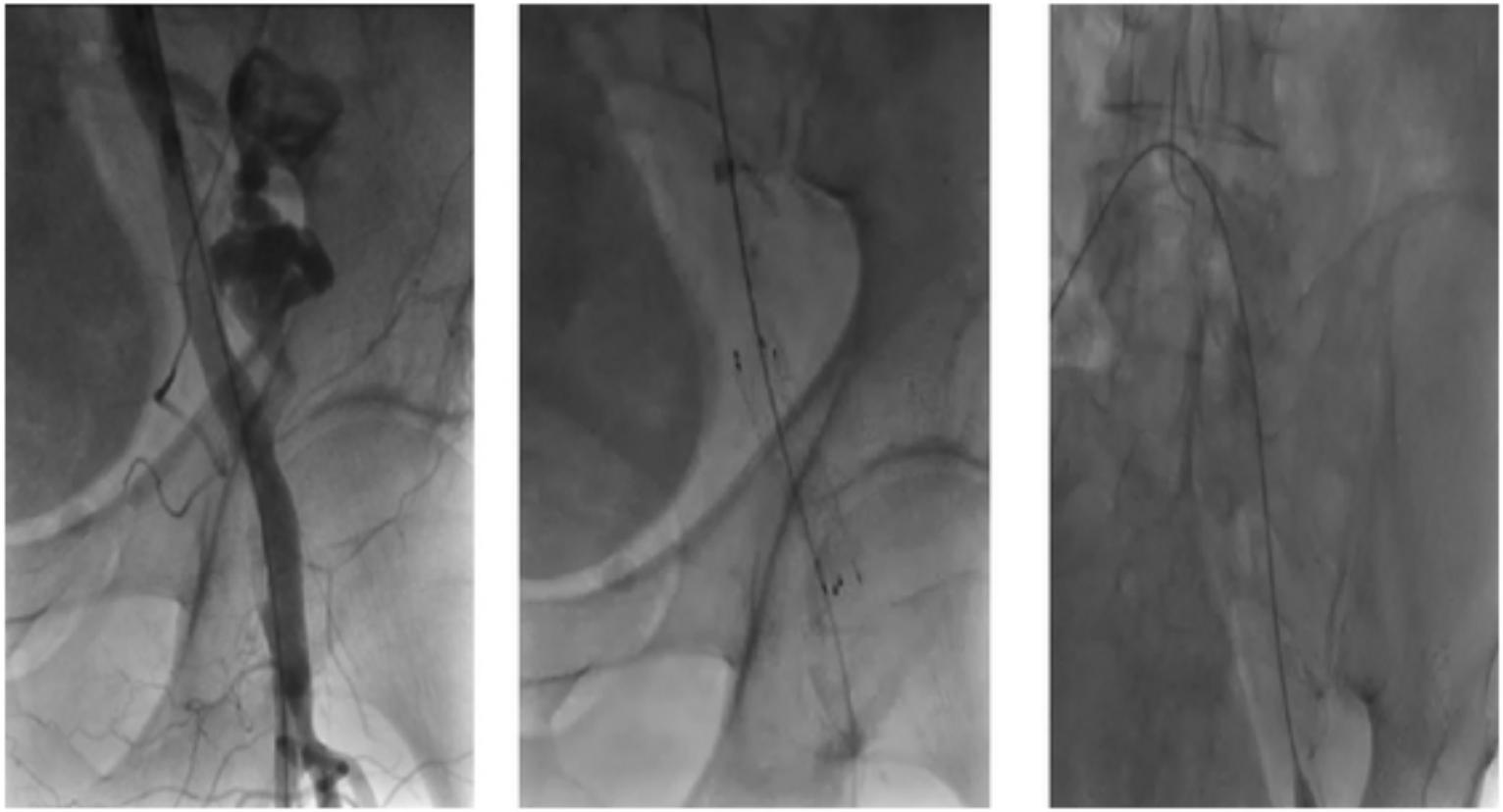


Figure 3.

Iliac perforation. **(A)** Right external iliac artery rupture (arrow) following retraction of large-bore introducer sheath. **(B)** Peripheral angioplasty balloon inflation using crossover technique and **(C)** following covered stent implantation, delivered using crossover technique from left common femoral artery.

Figure 4: Perforation of left femoral artery and stent placement. A stent placement is easier and faster in presence of a crossover wire in the femoral artery.



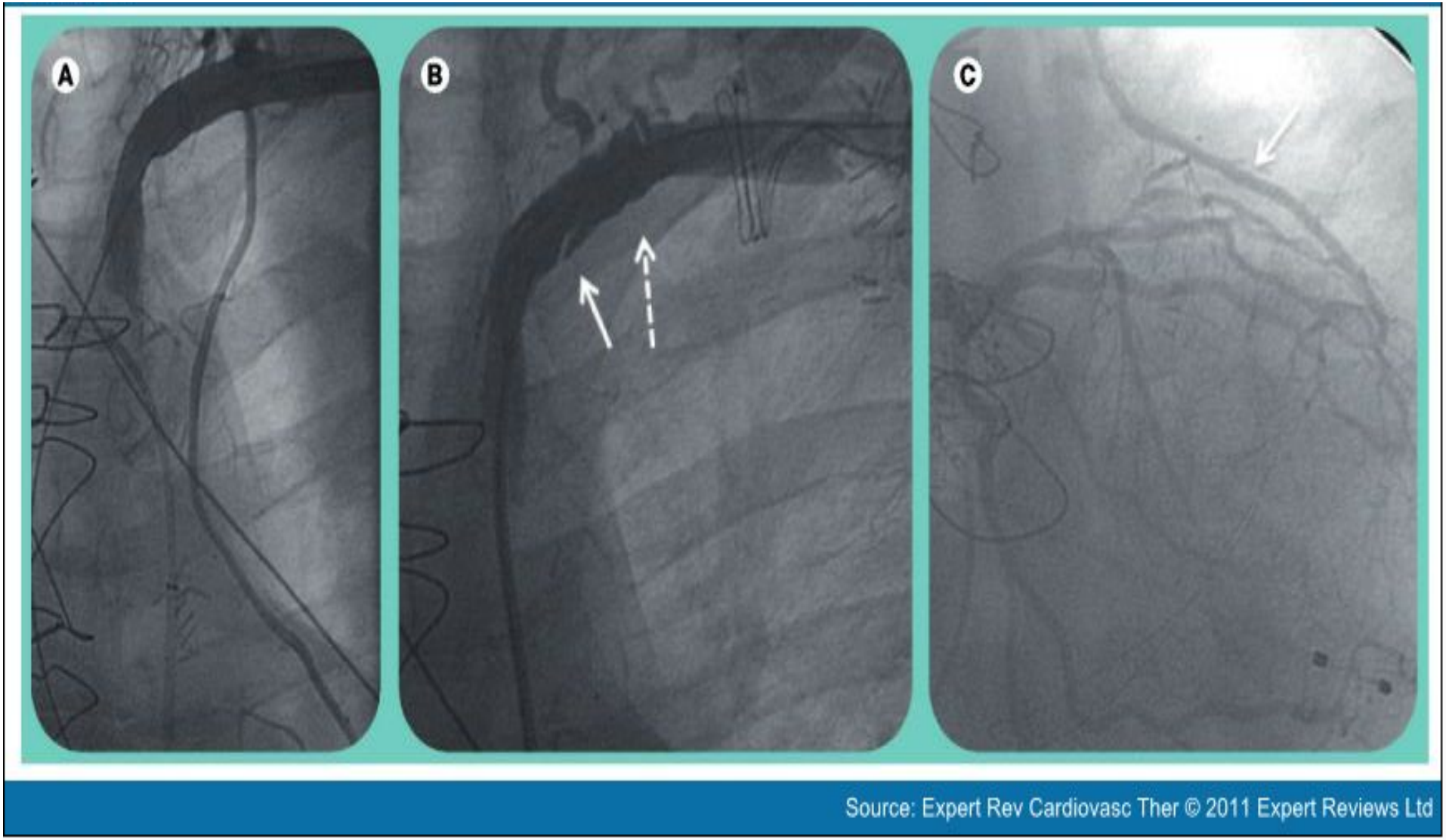
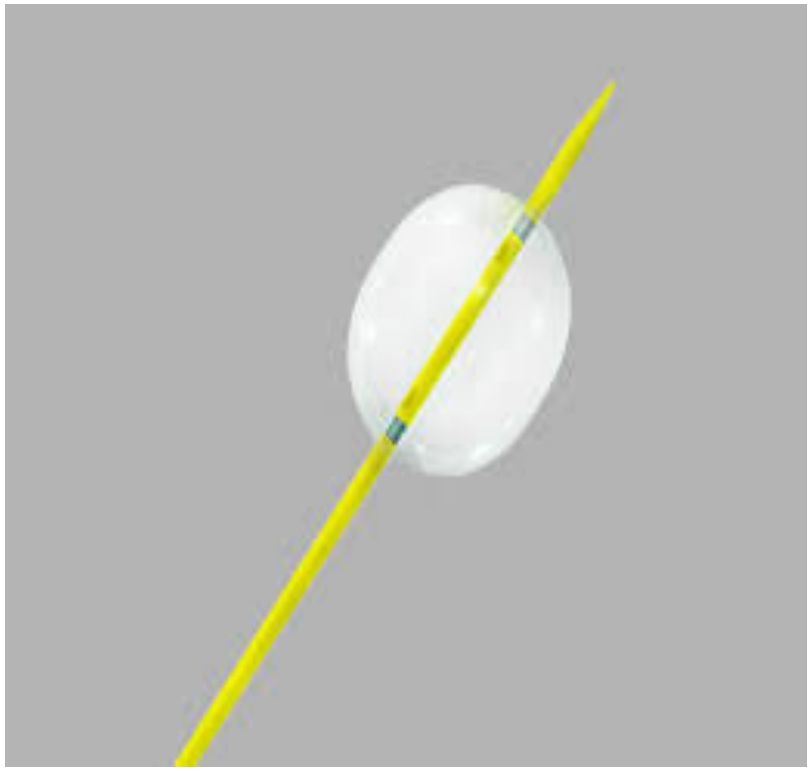


Figure 7.

Dissection of the left subclavian artery and left internal mammary artery during transaxillary access for transcatheter aortic valve implantation. **(A)** Patent, fully functional left internal mammary artery (LIMA) prior to axillary and subclavian instrumentation. **(B)** Dissection of the subclavian artery (solid arrow) resulting in acute closure of the LIMA (broken arrow) and **(C)** TIMI 3 flow in native left anterior descending artery/diagonal system with retrograde filling of the LIMA (arrow).

Compliant Occlusion Balloons

Use of compliant occlusion balloons during EVAR for AAA rupture.



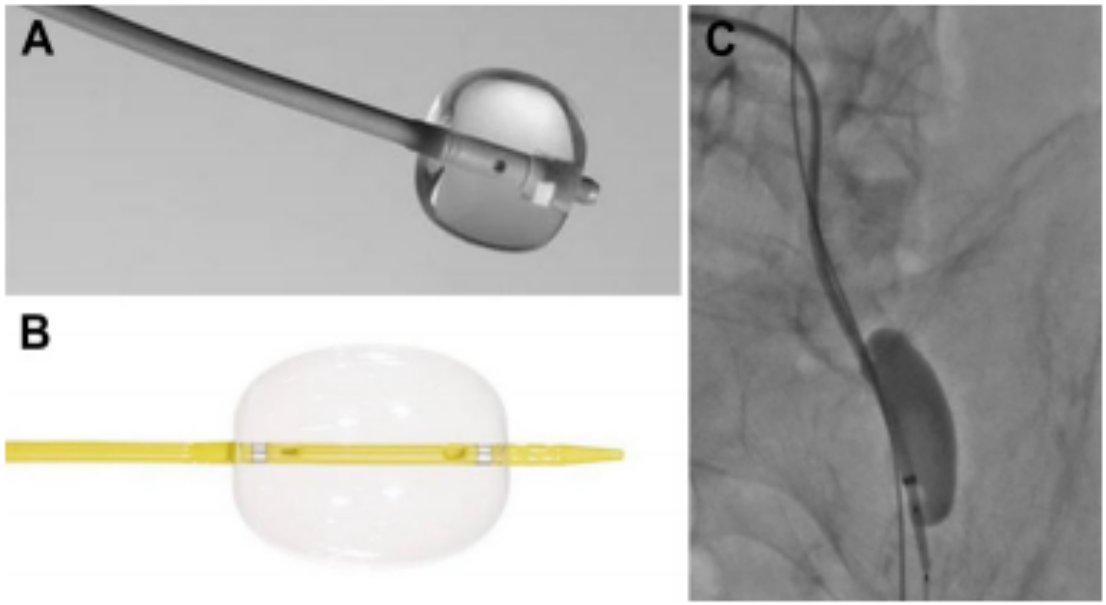


Figure 4. Examples of Occlusion Balloon Catheters

Berenstein occlusion balloon catheter (Boston Scientific, Natick, Massachusetts) **(A)** and Coda Occlusion Balloon Catheter (Cook Medical Inc., Bloomington, Indiana) **(B)**. **(C)** Inflated occlusion balloon in the left femoral artery. Note that the balloon assumes the shape of the artery and expands longitudinally once the vessel walls are reached.

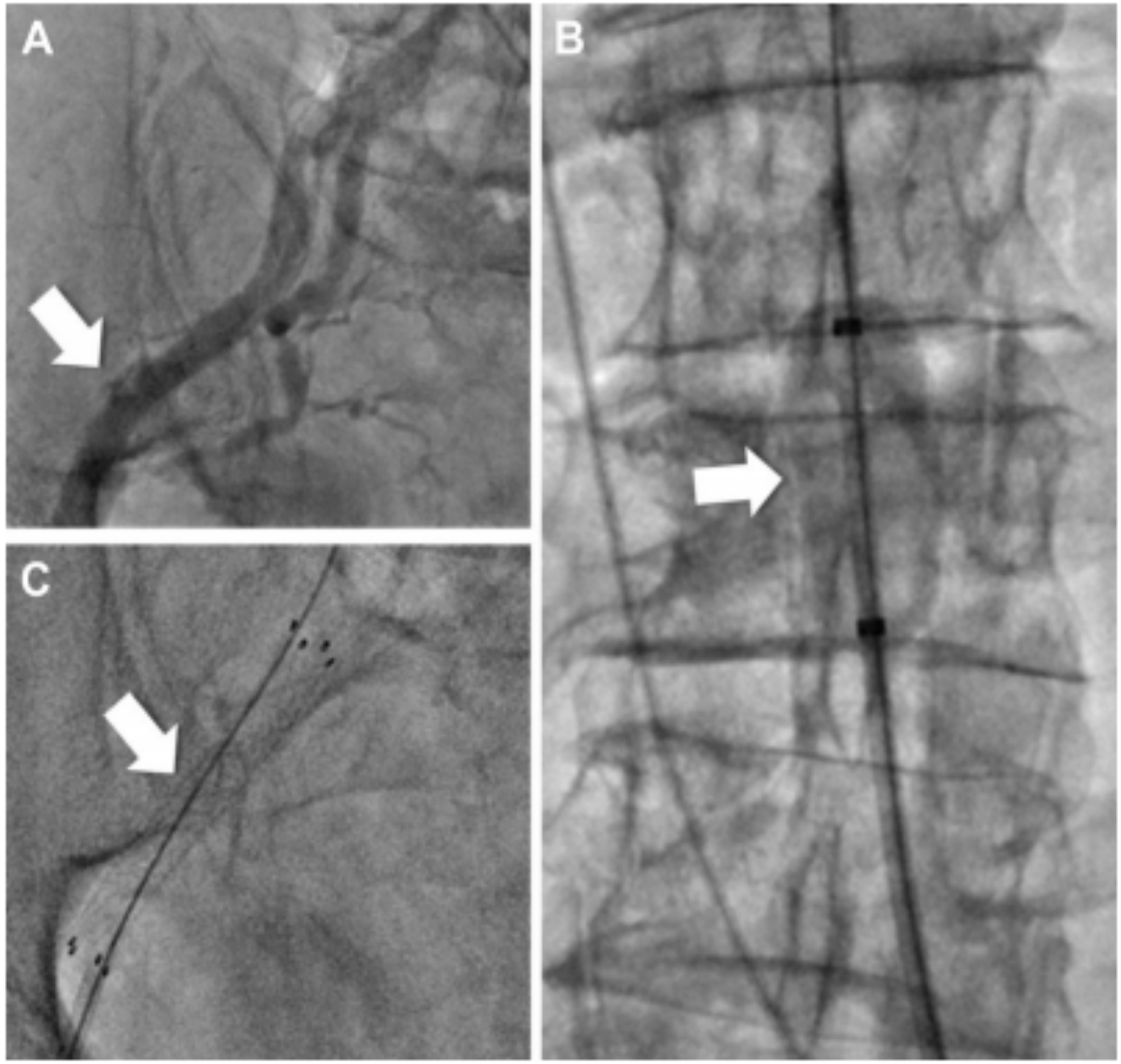


Figure 5. Occlusion of the Aorta to Treat a Femoral Bleeding

This patient had a perforated right common femoral artery **(A, arrow)**. An occlusion balloon was inflated in the lower abdominal aorta **(B, arrow)**, and a covered stent was implanted to treat the perforation **(C, arrow)**.

Vascular Solution

- Complete sealing of the vascular leak was obtained with no haemodynamic compromise.
- The patient did well afterwards (in hospital and 8 months later) and was discharge on day-6 following TAVI.

FLUENCY® Plus
(AngioMed, BARD)

GORE

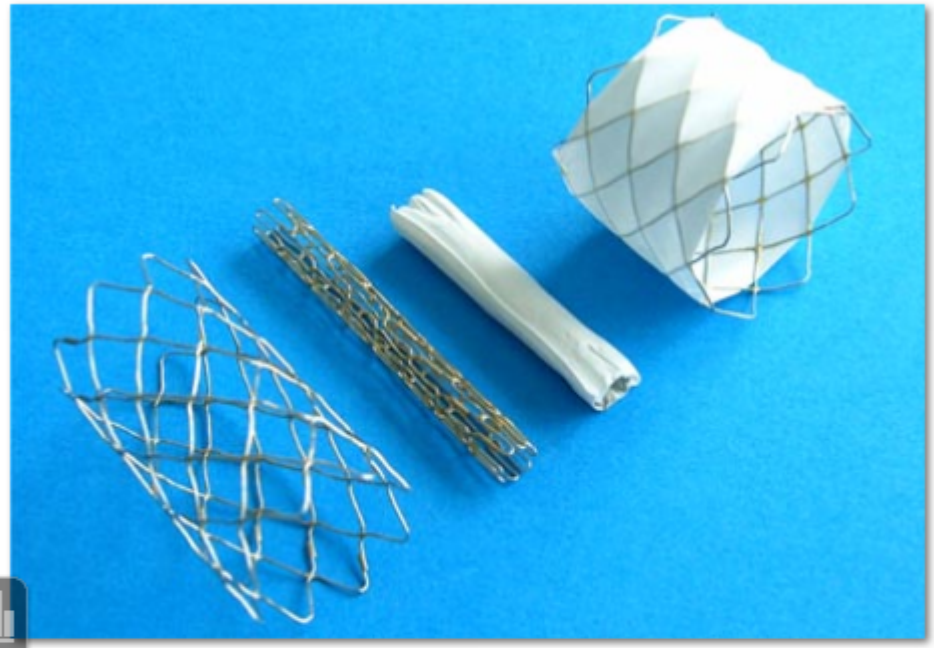
VIABAHN®

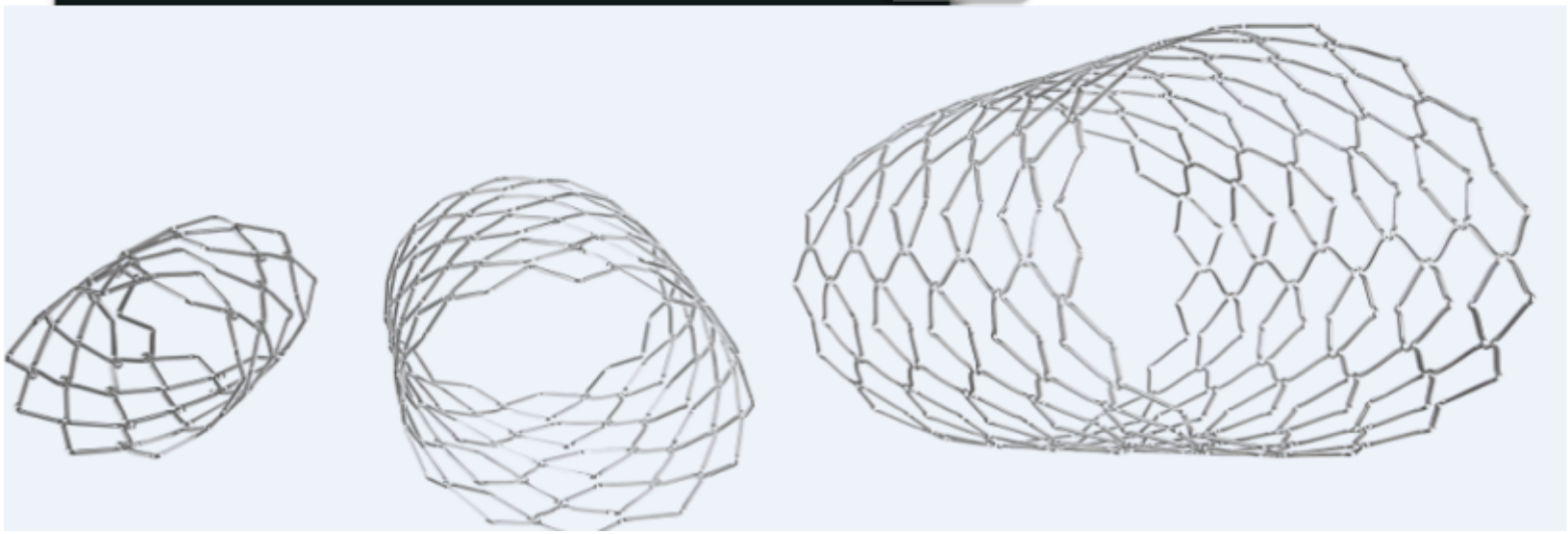
ENDOPROSTHESIS

Complicanze vascolari

- Asse iliaco-femorale
- Fallimento device percutanei di chiusura
- Dissezione aortica -rottura aortica
- Rottura anulus

ungere un titolo





Complicanze vascolari

- Asse iliaco-femorale
- Fallimento device percutanei di chiusura
- Dissezione aortica
- Rottura anulus

ROTTURA ANULUS

- Complicanza rara <1%
- Piu' frequente con valvole balloon expandable
- Post-dilatazione per trattamento leak paravalvolari
- Favorita da sovradilatazione aggressiva =>20%

Conclusions (2)

THE PARTNER II TRIAL

- Other important clinical findings with SAPIEN 3 (both S3HR & S3i) include:
  - **Major vascular complications:** ~5%
  - **Annular rupture:** ~0.2%
  - **Coronary obstruction:** ~0.3%
  - **New pacemakers:** ~10%

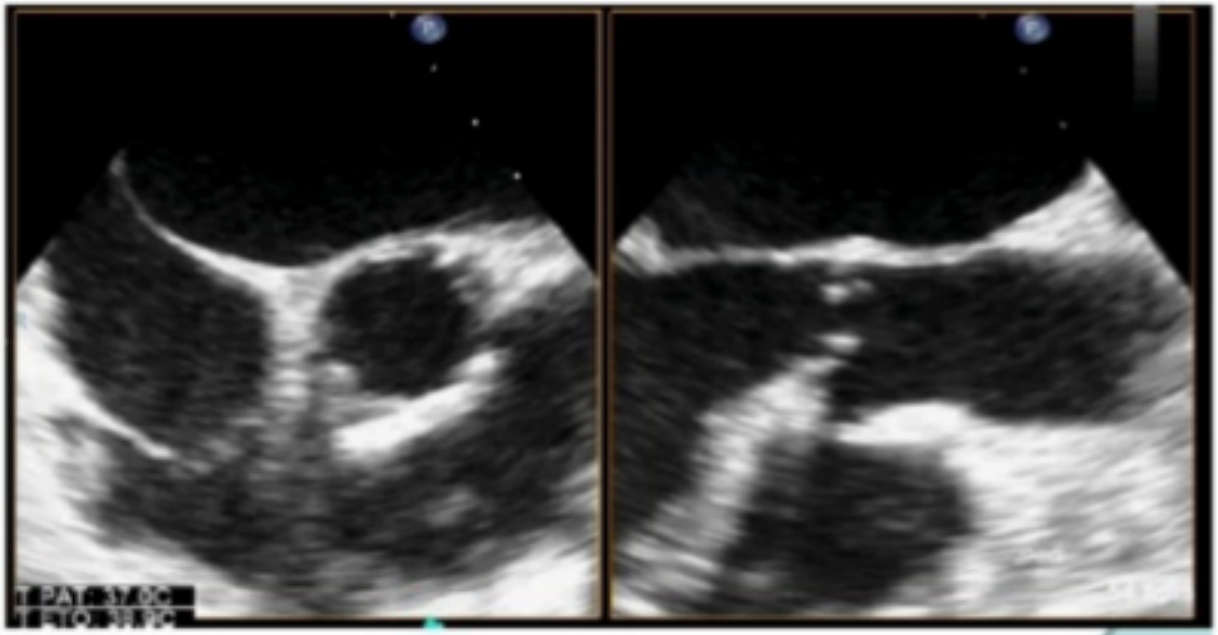
ROTTURA ANULUS
caratteristiche anatomiche predisponenti

- Anulus piccolo < 20 mm
- Radice aortica piccola
- Calcificazioni importanti lembi , anulus, LVOT
- Noduli di calcio >4-5 mm
- Valvola bicuspide calcifica
- IVS (subaortica)

ROTTURA ANULUS
prevenzione

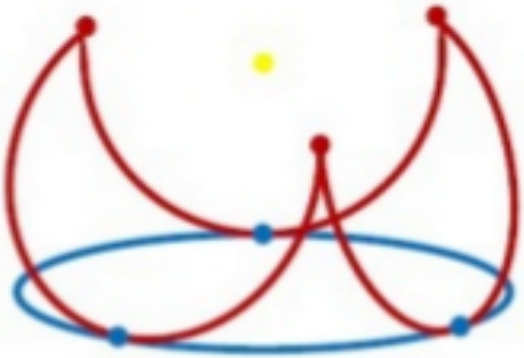
- Valutazione fattori predisponenti
- Scelta del tipo di valvola
- Scelta della misura
- Modifica del piano di impianto
- Evitare post-dilatazione

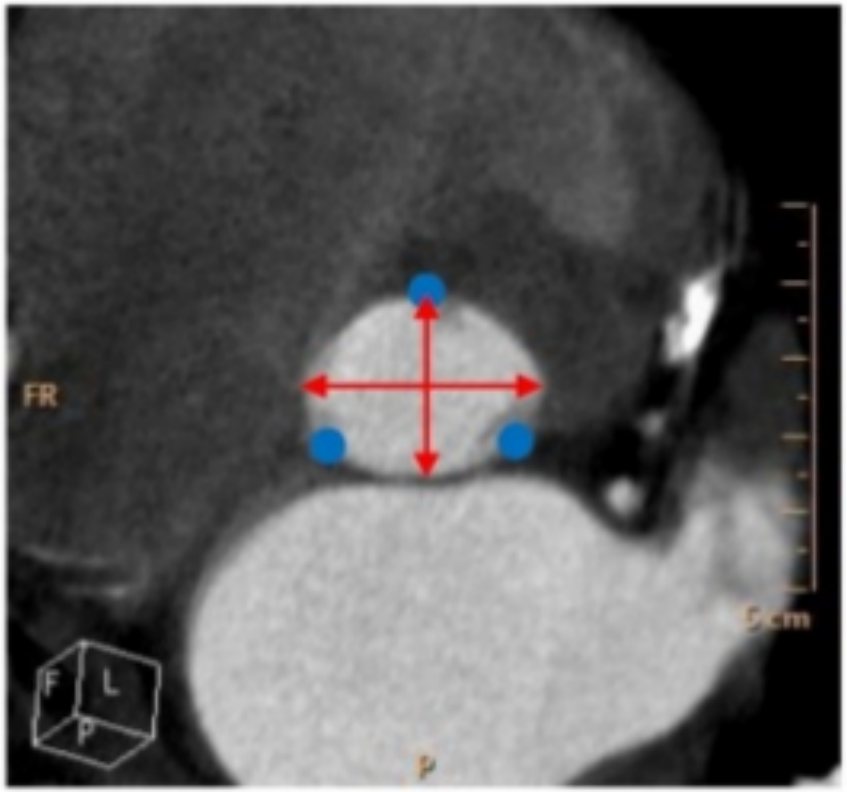
Echo is not isotropic



- ✓ Low resolution than CT scan
- ✓ Lower resolution with depth
- ✓ Large diameter not seen

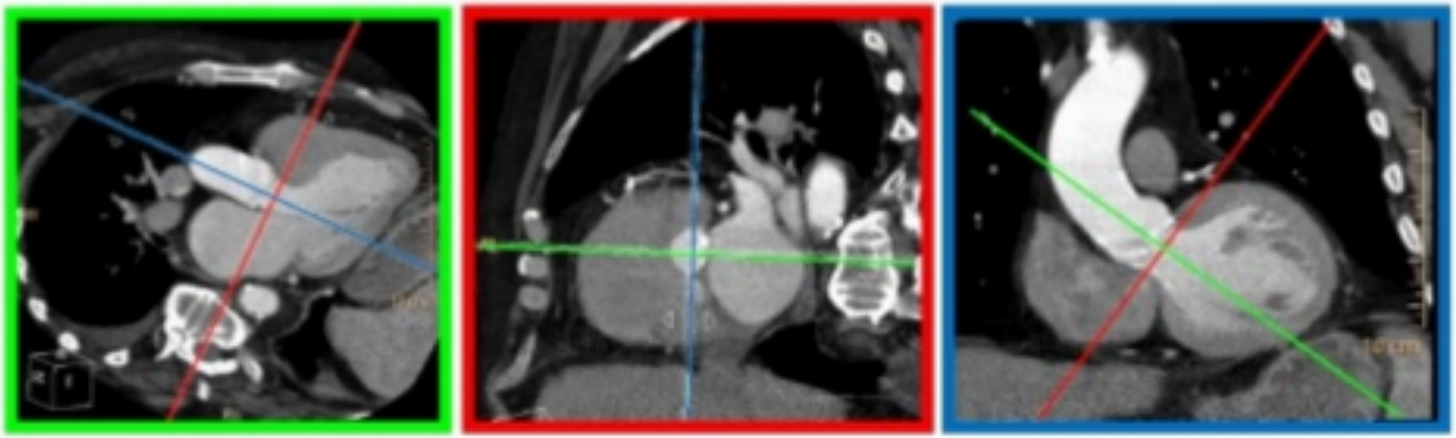
…and this crown is not circular



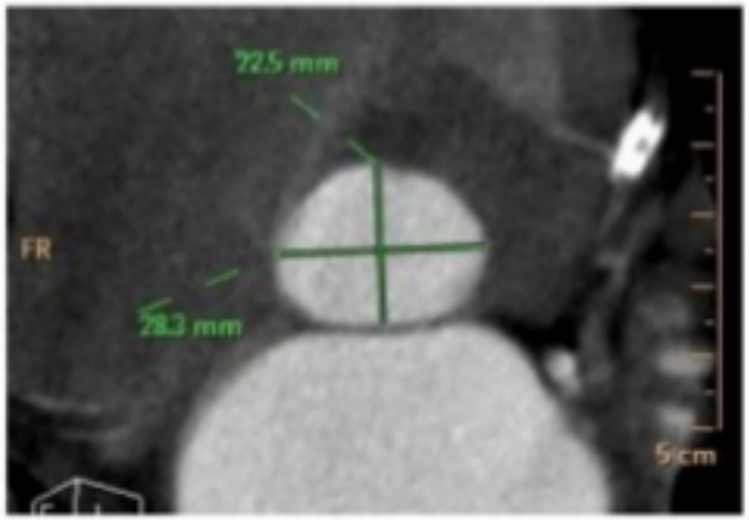


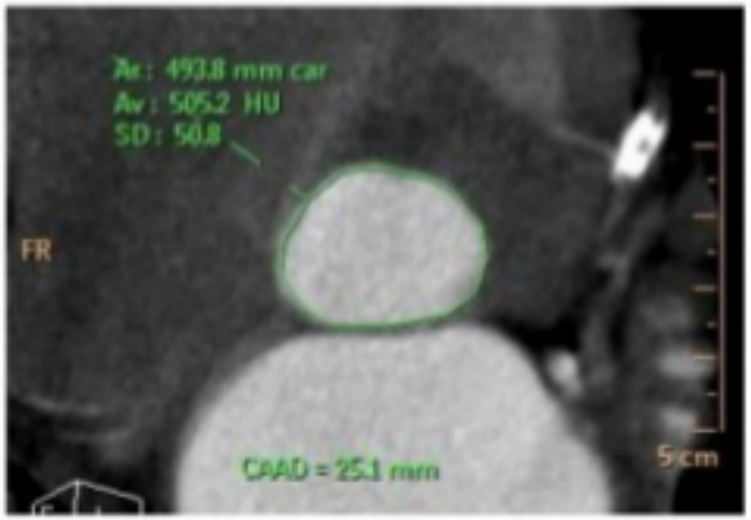
- ✓ Variable orientation (≤30°)
- ✓ Small diameter is often antero-posterior (= Echo)
- ✓ Large diameter grossly lateral
- ✓ Variability between the 2 diamètres (4-5mm, from 1 to 8mm)

CT scan is 3D & isotropic



- Resolution = 0.5 mm in all directions
- May help to determine the optimal view





ROTTURA ANULUS

- Anche silente per piccole fissurazioni
- Evento catastrofico
- Tamponamento cardiaco
- Ematoma periaortico

ROTTURA ANULUS

- Strategia conservativa (morti improvvise F. UP)
- Drenaggio pericardico
- CCH e supporto circolatorio femoro-femorale.
- Valve in valve (non raccomandata).

ROTTURA ANULUS

J Invasive Cardiol. 2013 Aug;25(8):409-10.

Valve-in-valve implantation for aortic annular rupture complicating transcatheter aortic valve replacement (TAVR).

Yu Y[1], Vallely M, Ng MK.

Author information

Abstract

An 83-year-old woman with multiple comorbidities and severe aortic stenosis presented with recurrent pulmonary edema. In light of her high surgical risk, a percutaneous strategy for her aortic stenosis was decided. Transcatheter aortic valve replacement using a balloon-expandable Edwards Sapien XT valve was performed under rapid ventricular pacing. Soon after valve deployment, the patient went into hemodynamic collapse due to annular root rupture with pericardial tamponade, necessitating urgent pericardial decompression. Using a valve-in-valve technique, with the deployment of a second Edward Sapien XT valve inside the first valve, the annular root rupture was successfully sealed leading to hemodynamic recovery.

GRAZIE PER L'ATTENZIONE