

Con il Patrocinio di



Malattia coronarica cronica in paziente già sottoposto a PCI: dallo studio Compass alla pratica clinica

Strategie vincenti nella gestione
della terapia antitrombotica nel paziente
con cardiopatia ischemica cronica

PAZIENTE CON VASCULOPATIA PERIFERICA E STORIA DI PCI

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U.O Cardiologia - Emodinamica Interventistica

O.C. Castelfranco Veneto

AULSS 2 Marca Trevigiana

STORIA CLINICA

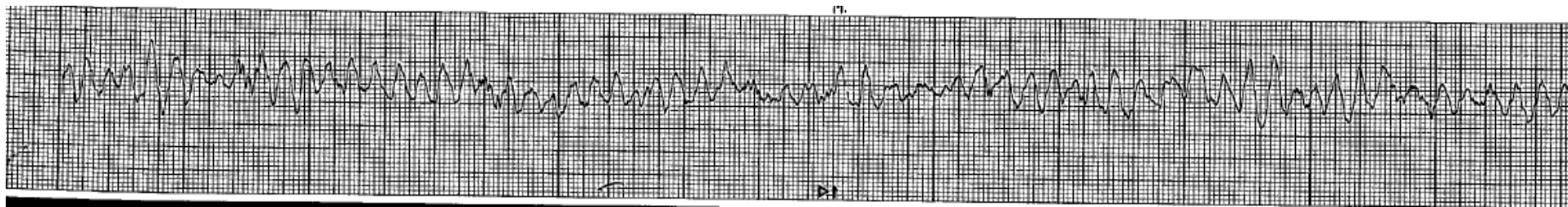
- **B.S , M, n. 1942**
- **Iperensione arteriosa**
- **Diabete tipo 2 in terapia con ipoglicemizzanti orali**
- **Ipercolesterolemia**
- **Ex fumatore**

- **2007: TEA femorale destra**
- **2008: TEA carotide interna destra**
- **2008: STEMI inferiore (non terapia riperfusiva in acuto)**
- **2008: duplice CABG (LIMA-IVA, Radiale-D1)**
- **2012: bypass axillofemorale dx per ischemia critica**
- **2012: stenting succlavio sinistro per furto permanente di succlavia**
- **2014: ecocardiogramma: ventricolo sx di normali dimensioni, acinesia inferiore con FE 50%, lieve disfunzione ventricolare dx (TAPSE 16 mm), lieve insufficienza mitralica, aortosclerosi**

TERAPIA DOMICILIARE

- **ASA 100 mg**
- **Carvedilolo 6,25 mg x 2**
- **Ranolazina 375 mg x 2**
- **Furosemide 25 mg**
- **Simvastatina/Ezetimibe 40/10 mg**
- **Ramipril 2,5 mg**
- **Nitrato TD 10 mg**

Malattia coronarica cronica in paziente già sottoposto a PCI: dallo studio Compass alla pratica clinica



STORIA CLINICA

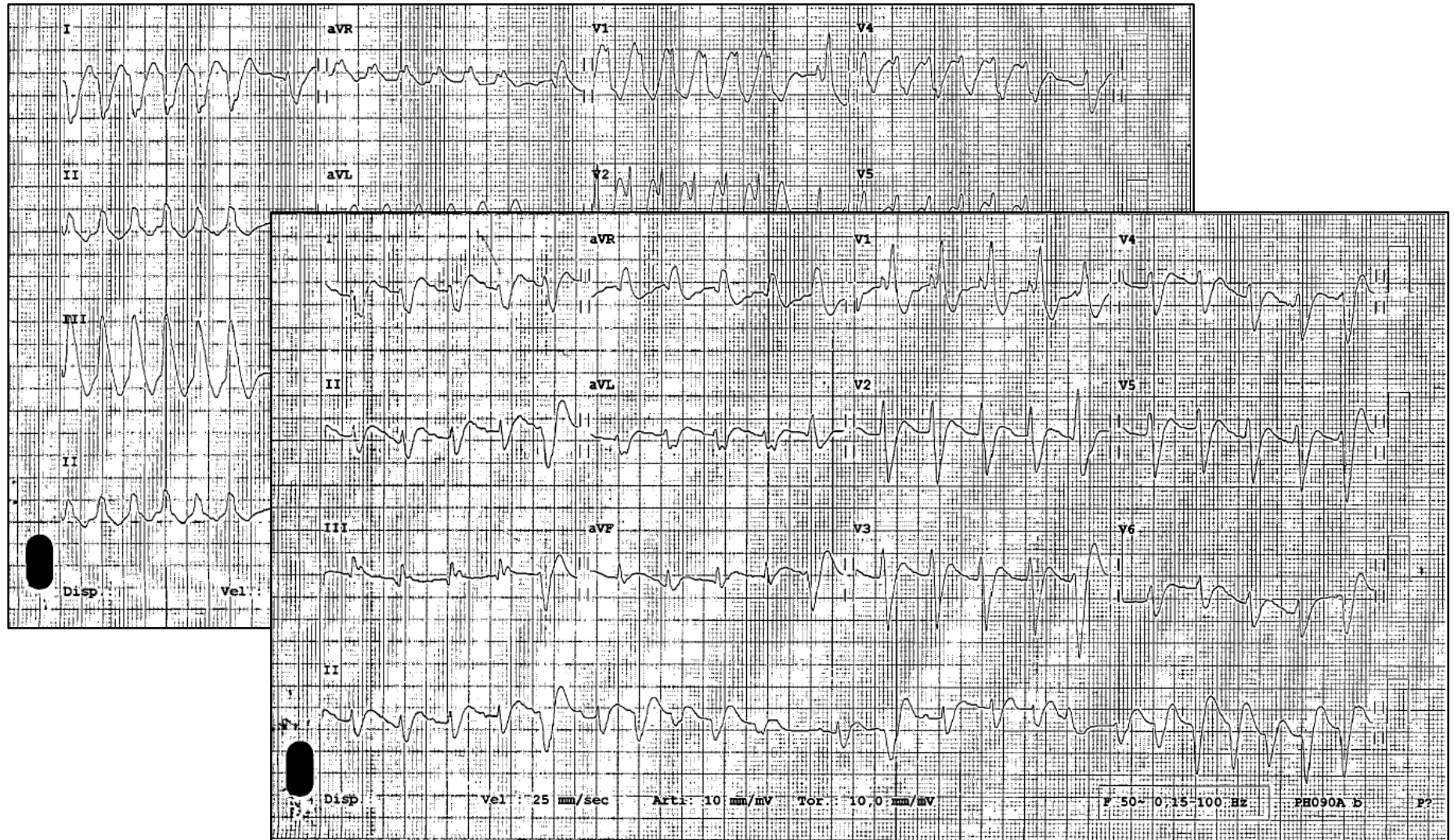
2014: intervento di rimozione di protesi axillofemorale per retrazione fibrotica invalidante

***IN 3° GIORNATA POSTOPERATORIA DOLORE TORACICO
CON FIBRILLAZIONE VENTRICOLARE RECIDIVANTE
DC SHOCK 200 J MULTIPLI CON RIPRESA DI POLSO***

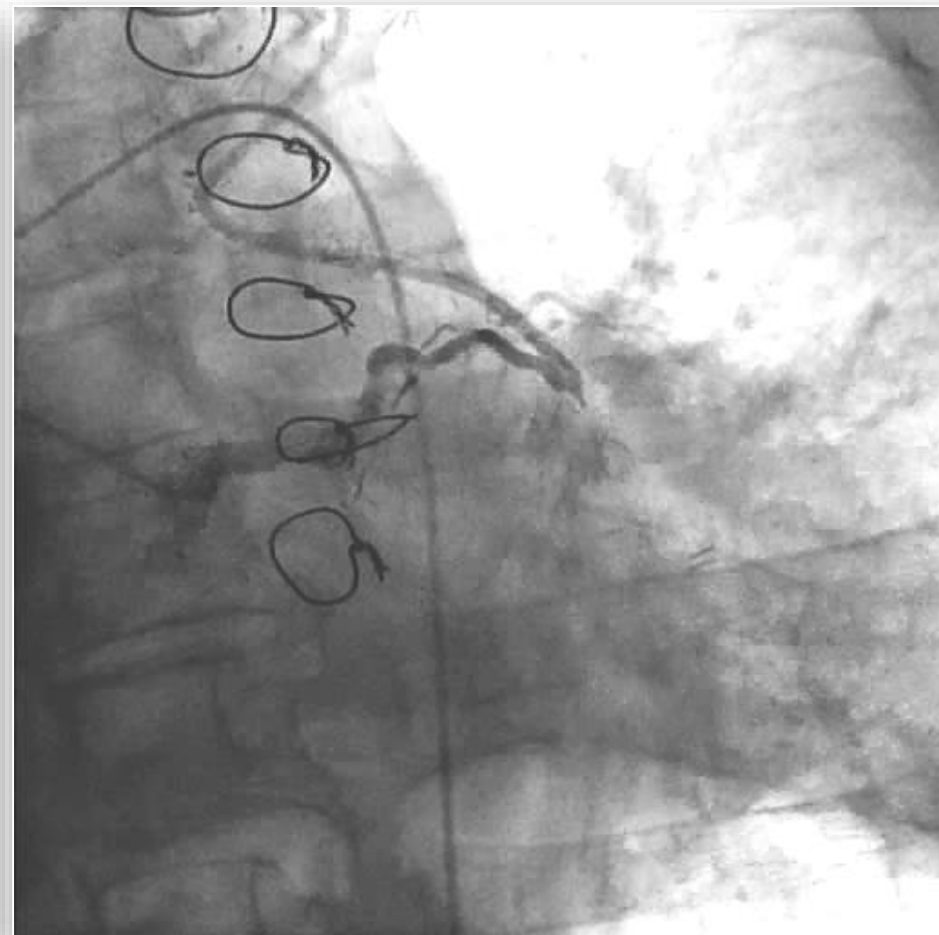
Ecocardiogramma: acinesia del setto interventricolare medioapicale (nuovo riscontro), acinesia inferiore, Fevsx 40%

Esami ematochimici: Hb 12,7 g/dl; Na meq/L, K 3,6 meq/L

ECG

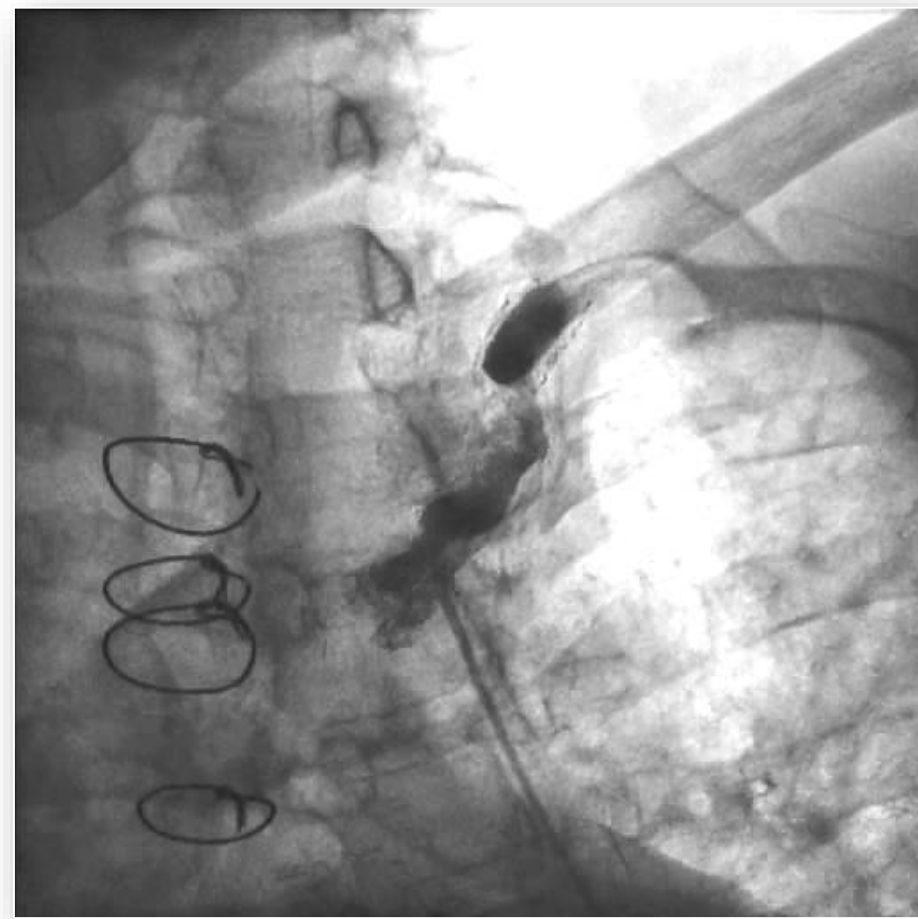
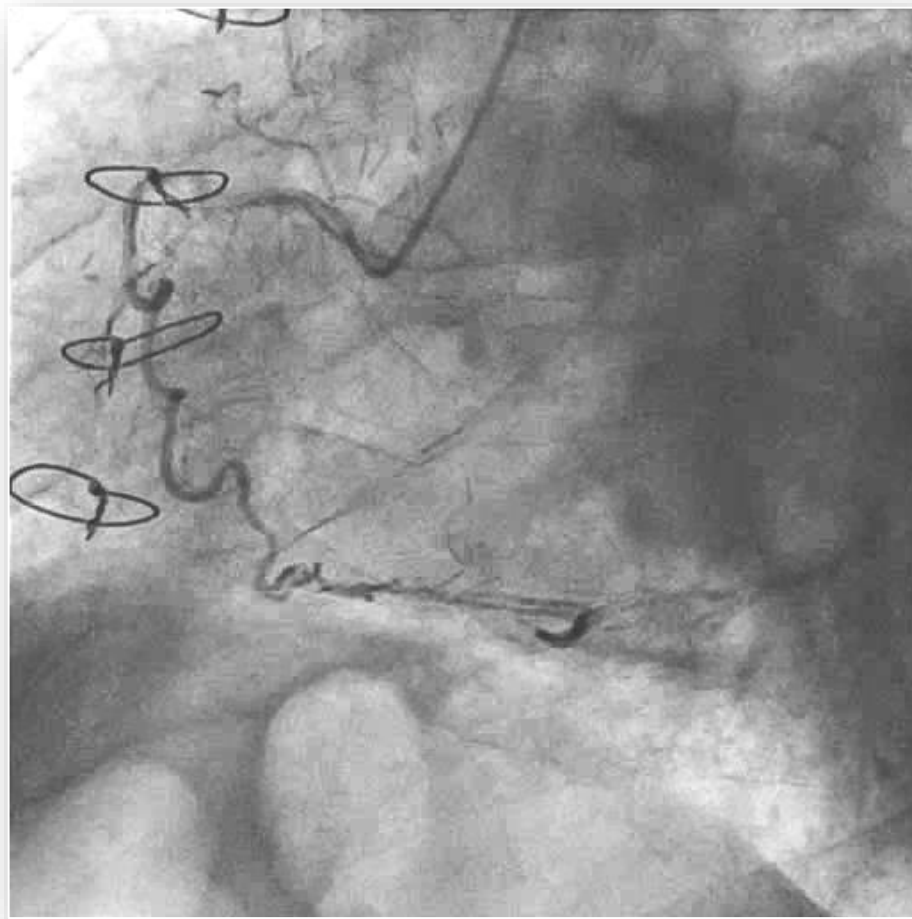


ANGIO BASELINE



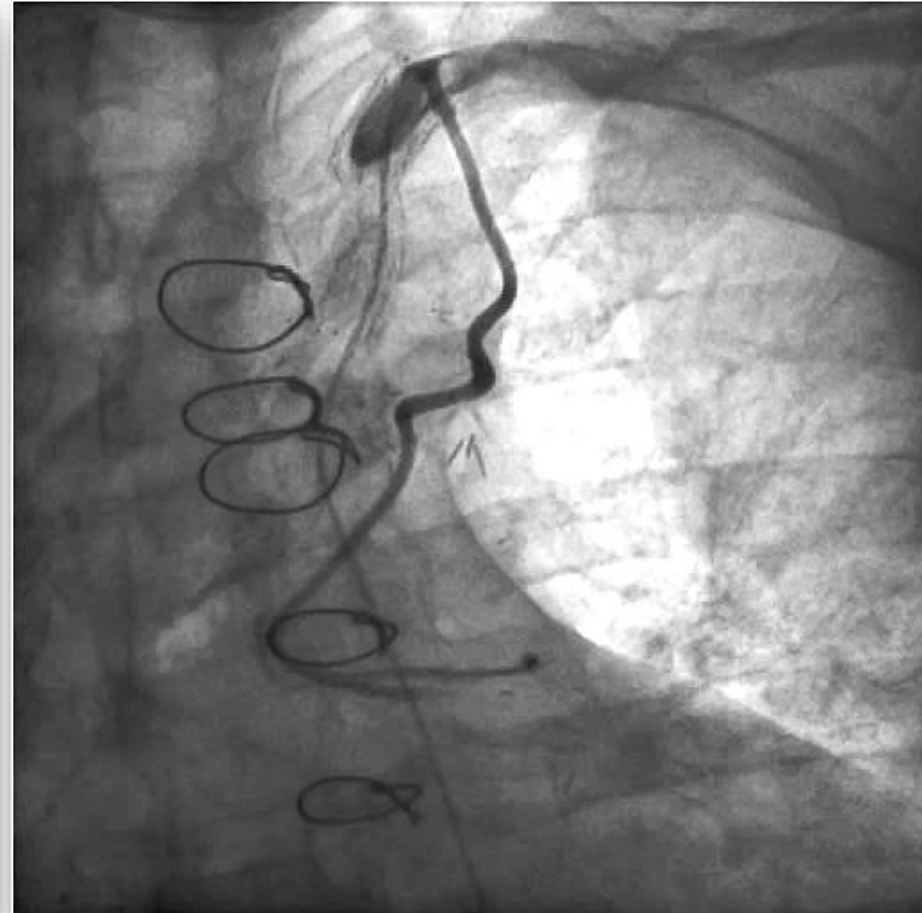
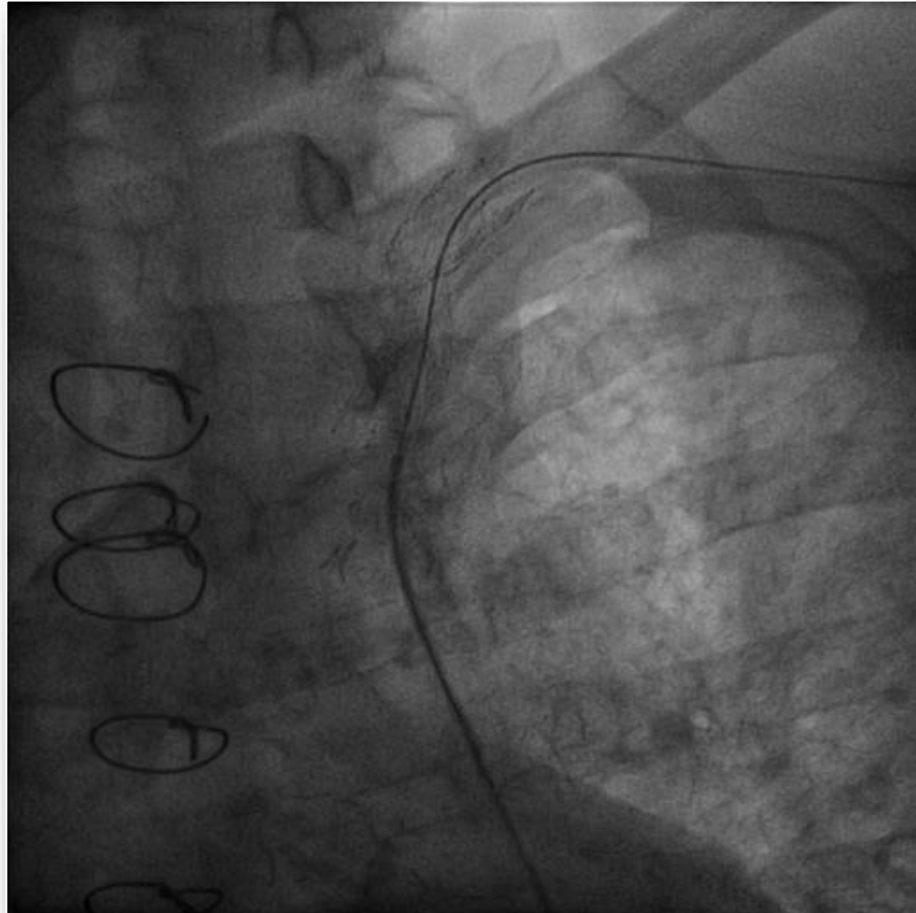
PERFUSIONE RETROGRADA DEL GRAFT ARTERIOSO PER IVA-D1

ANGIO BASELINE

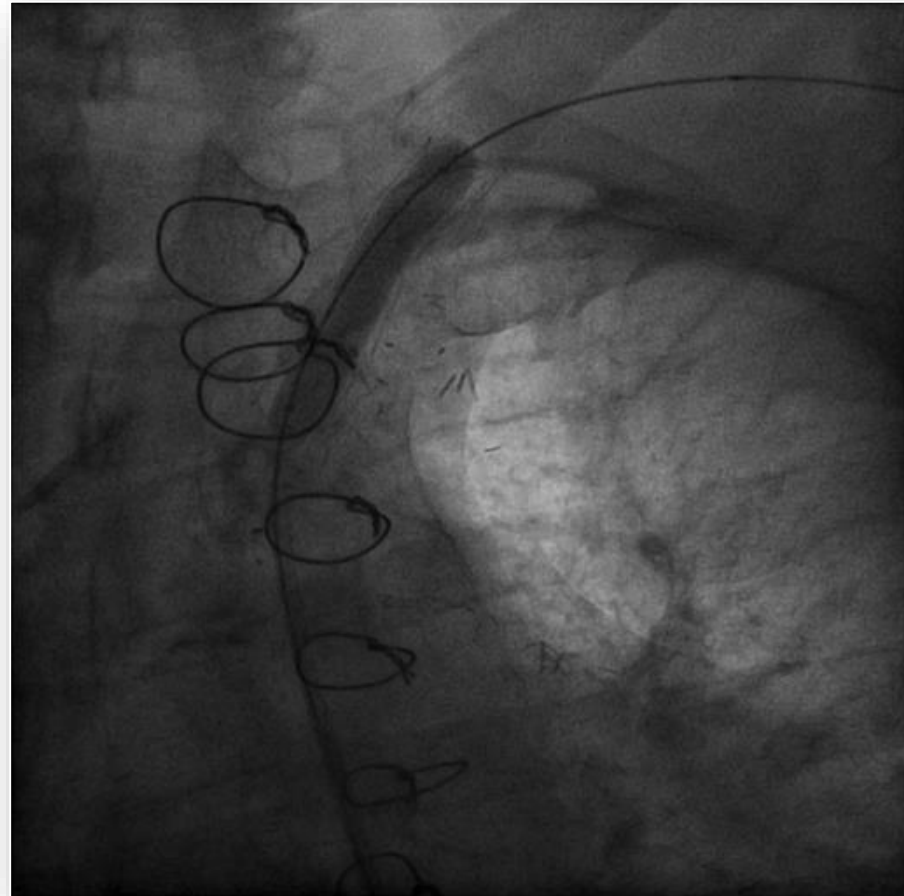
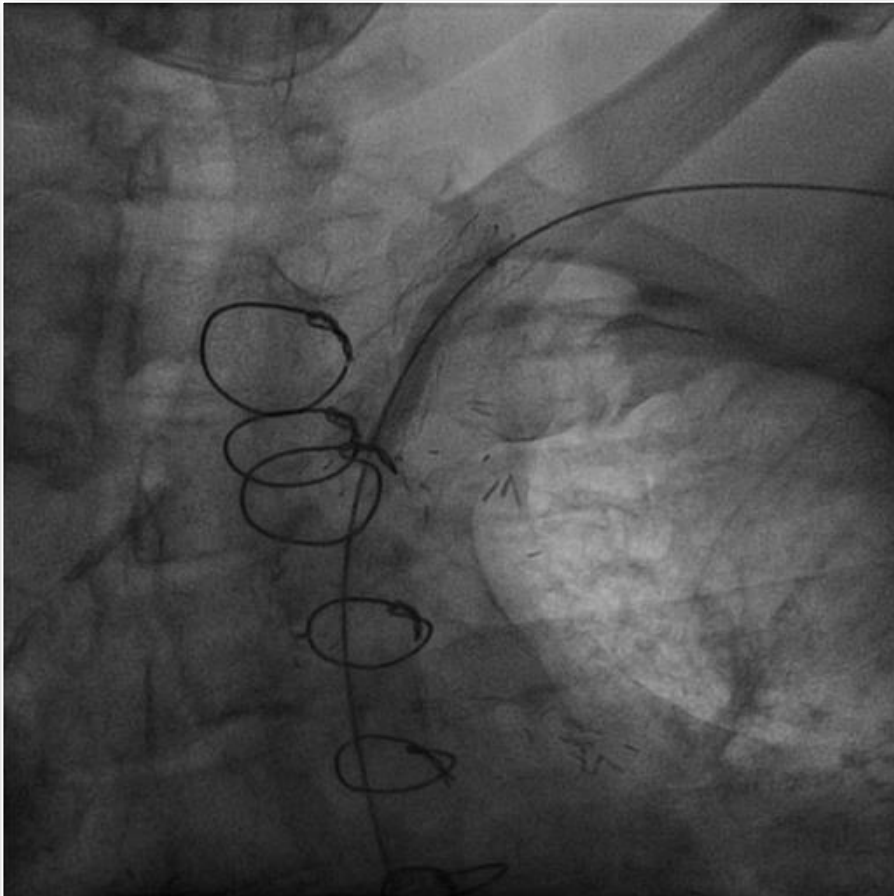


IOPERFUSIONE DEL GRAFT ARTERIOSO PER STENOSI SUBOCCLUSIVA DELLA SUCCLAVIA

ANGIO BASELINE

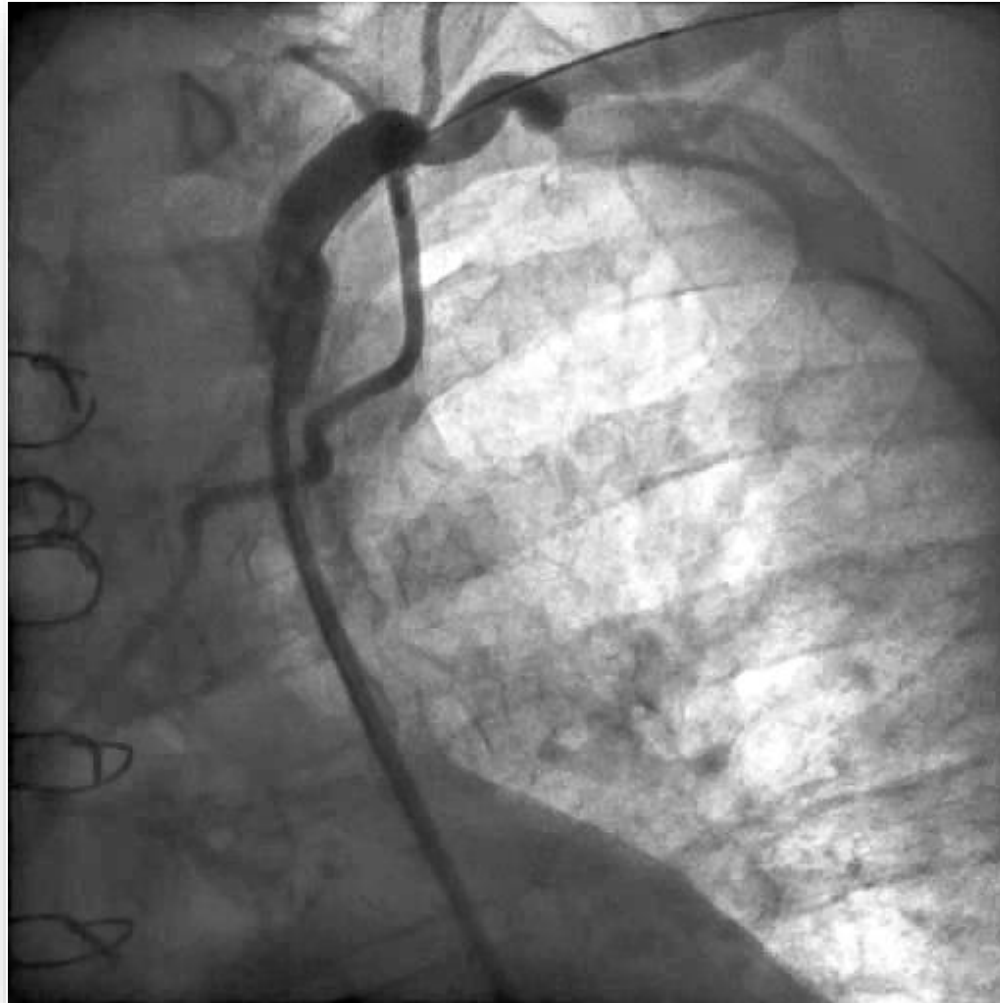


PTA SUCCLAVIA SINISTRA

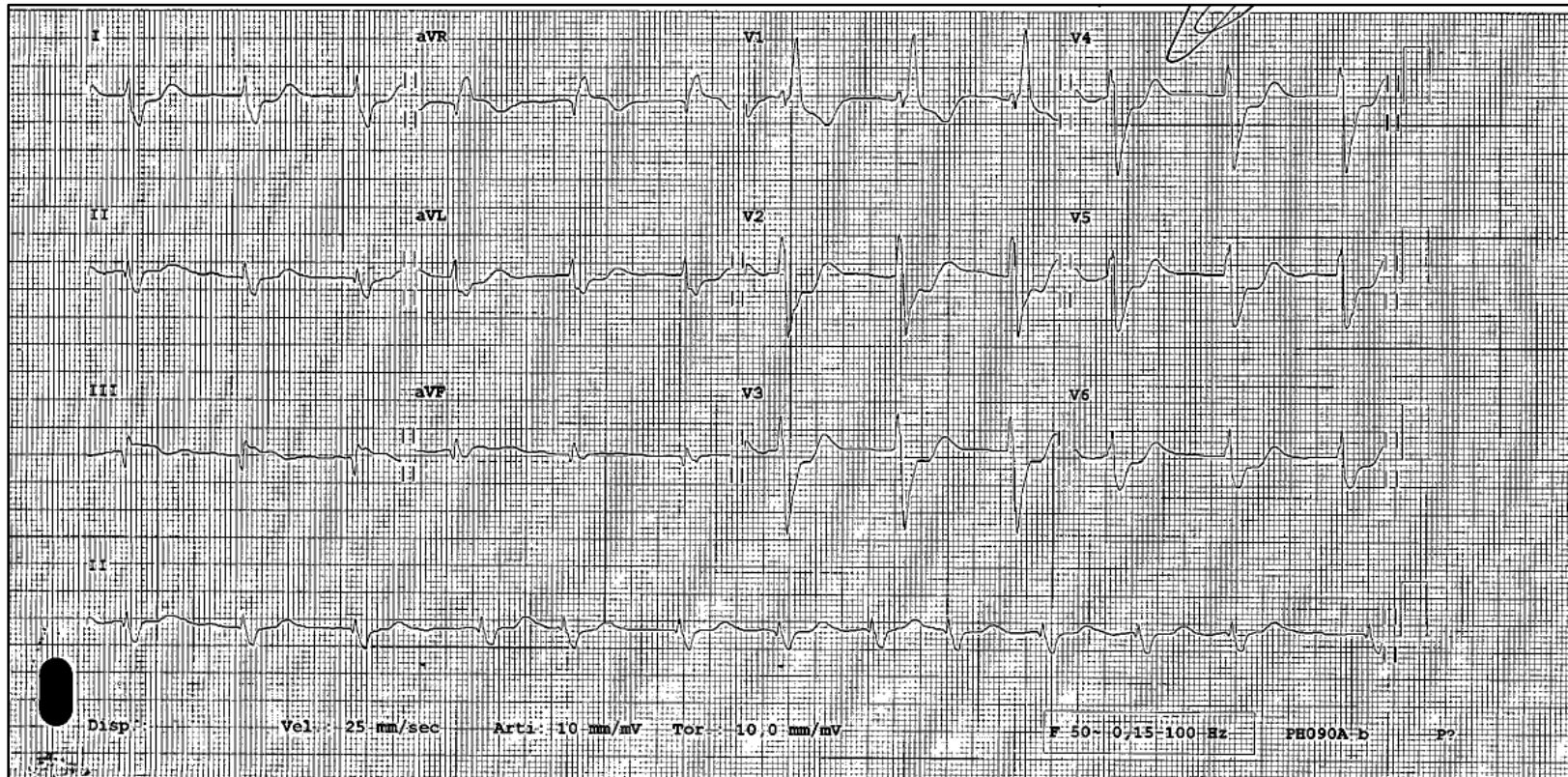


***Introduttore Destination 7 Fr 90 cm, guida Supracore
Palloni Evercross 5x30 mm e 8x40 mm***

ANGIO POST PTA

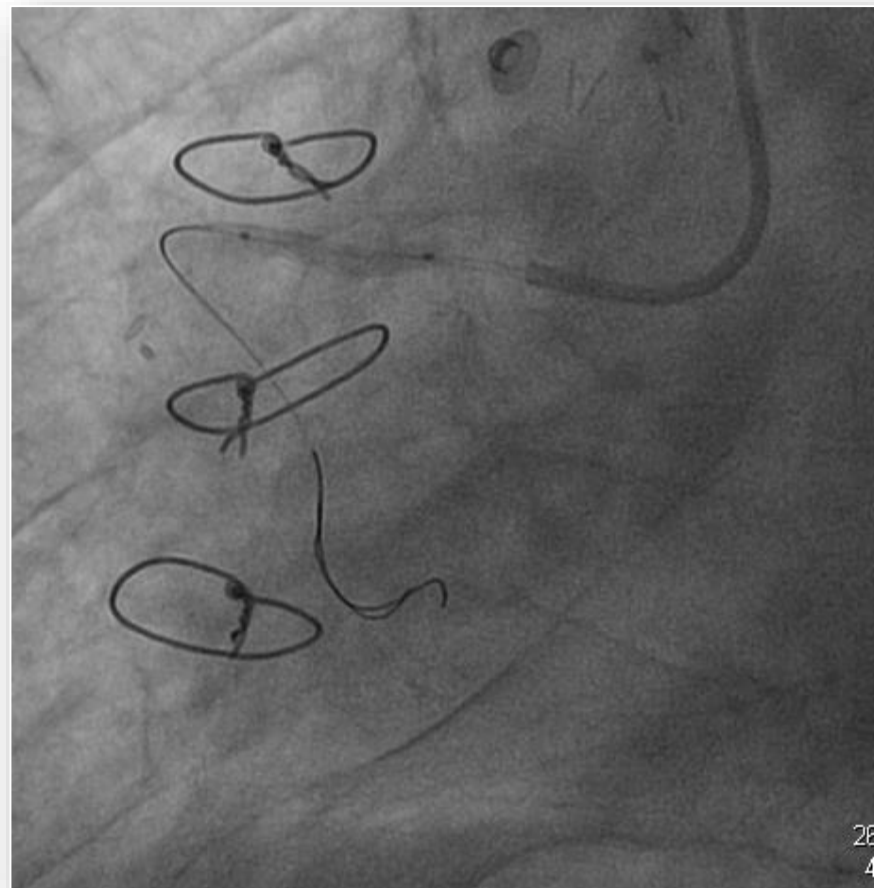
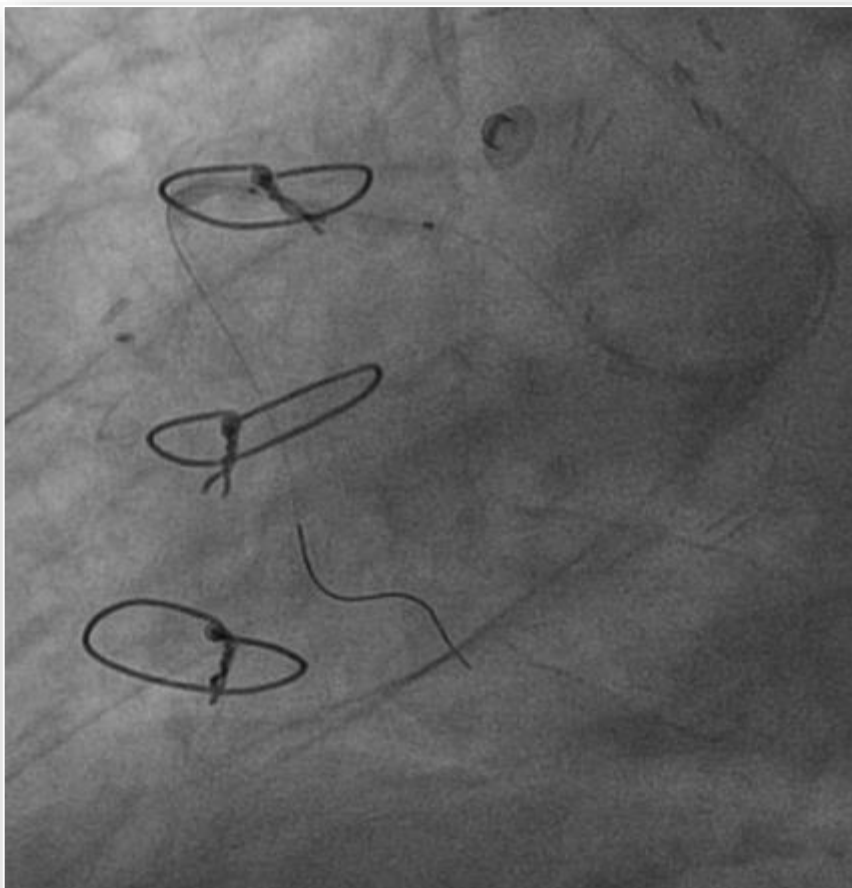


ECG POST PTA SUCCLAVIA



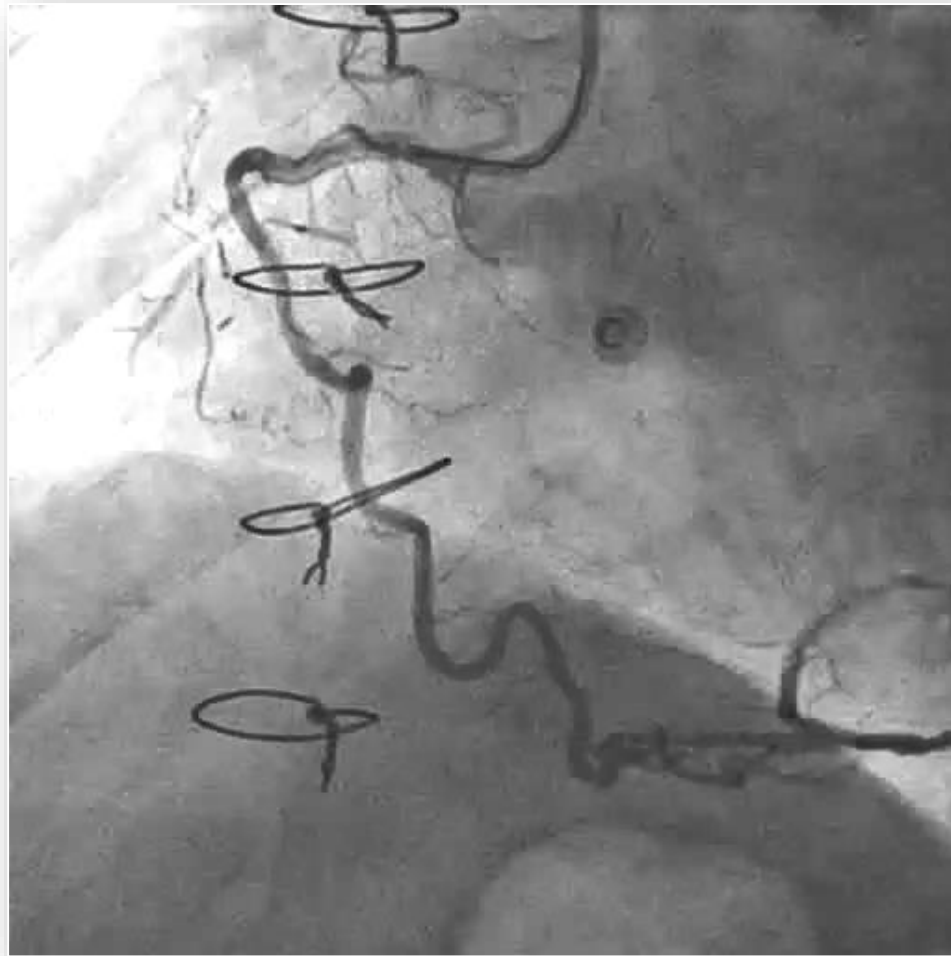
....persistenza di dolore toracico...

PTCA CORONARIA DESTRA



***Introduttore H-stick 6 Fr, guida BMW
Dilatazione con NC 2.5x12 mm, DES 2.75x18 mm***

ANGIO POST PTCA CDX



...AL RIENTRO IN UTIC...

- **Paziente asintomatico**
- **Emodinamica stabile**
- **Ecocardiogramma: ventricolo sinistro di normali dimensioni, acinesia inferiore con FE 52%, sezioni destre normali, aortosclerosi con gradiente transvalvolare 10 mm Hg**



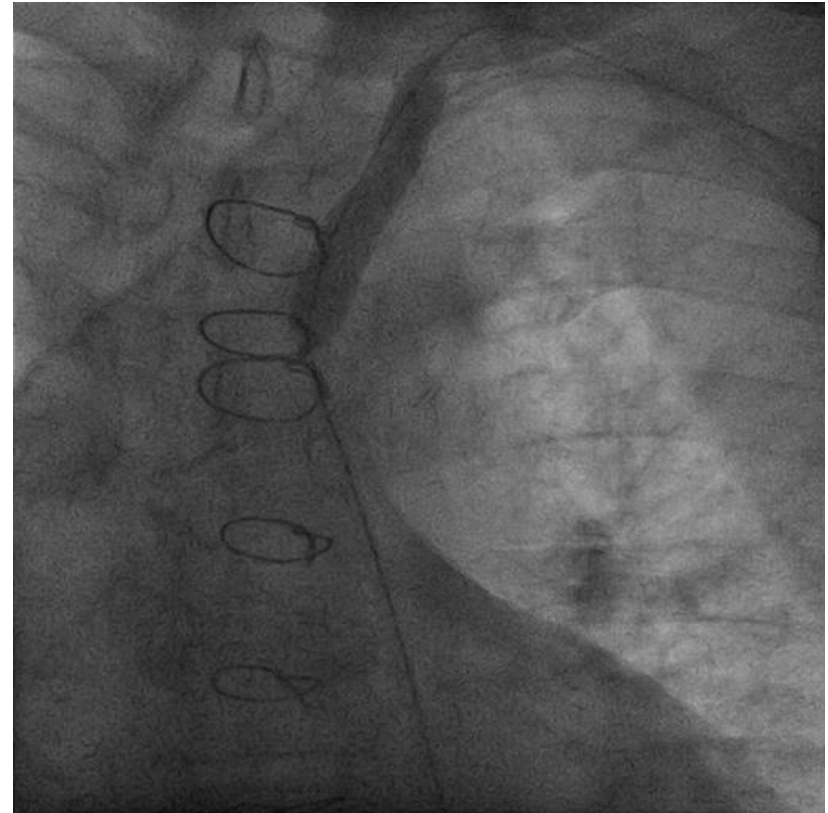
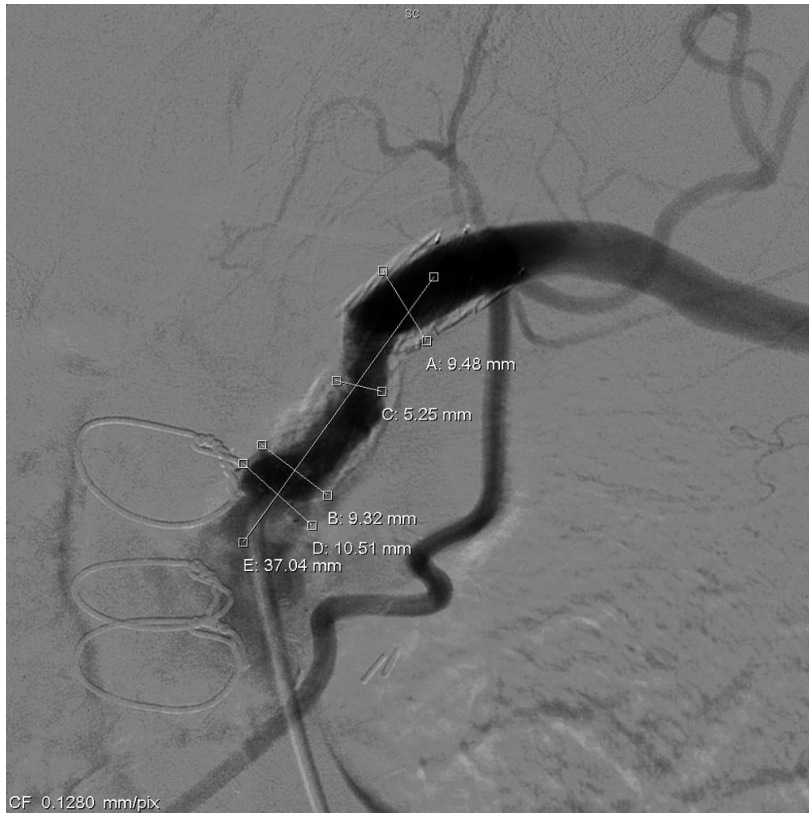
TERAPIA ALLA DIMISSIONE

- ***ASA 100 mg***
- ***Clopidogrel 75 mg***
- ***Carvedilolo 6,25 mg 1 x 2***
- ***Furosemide 25 mg***
- ***Amiodarone 200 mg***
- ***Lansoprazolo 30 mg***
- ***Allopurinolo 150 mg***
- ***Ramipril 2,5 mg***

ANGIO SUCCLAVIA- CONTROLLO

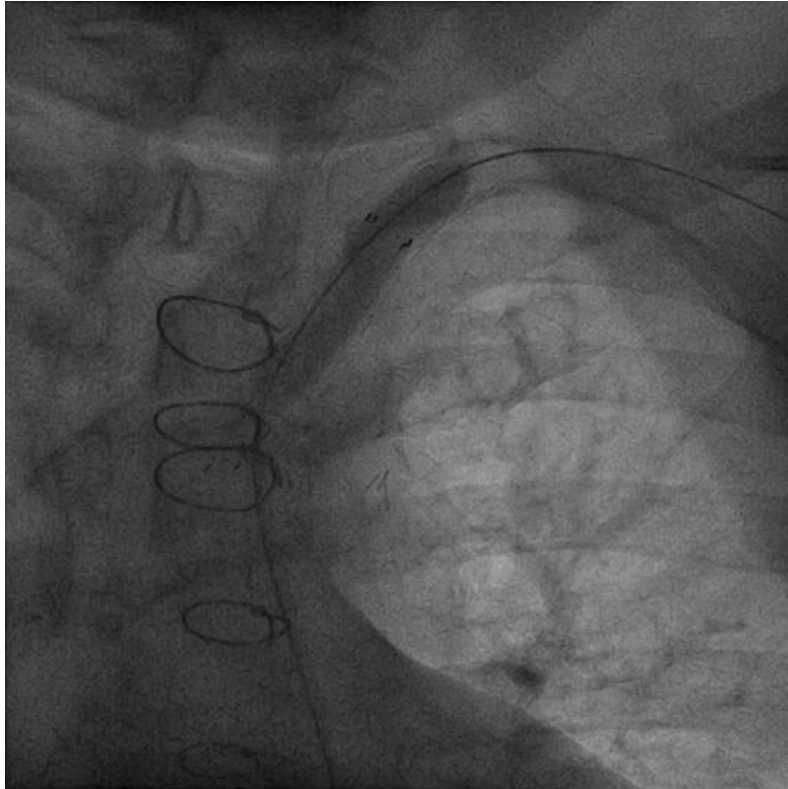


RE-STENTING SUCCLAVIA SINISTRA



***Introduttore Destination 7 Fr 90 cm, guida Supracore
Dilatazione con pallone 10x40 mm***

RE-STENTING SUCCLAVIA SINISTRA



***Stent autoespandibile 12x40 mm
Postdilatazione con pallone 10x40 mm***

FOLLOW UP

Visita di controllo 2015: paziente asintomatico per angina

Classe NYHA I, claudicatio dx 500 m

Ecocardiogramma 2016: Fevsx 50%, stenosi aortica con AVA 1,7 cm²

Visita di controllo 2017: angina da sforzo moderato (CCS II)

Ecocardiogramma: Fevsx 55%, stenosi aortica moderata (AVA 1,3 cm²)

Terapia: aggiunto nitrato TD

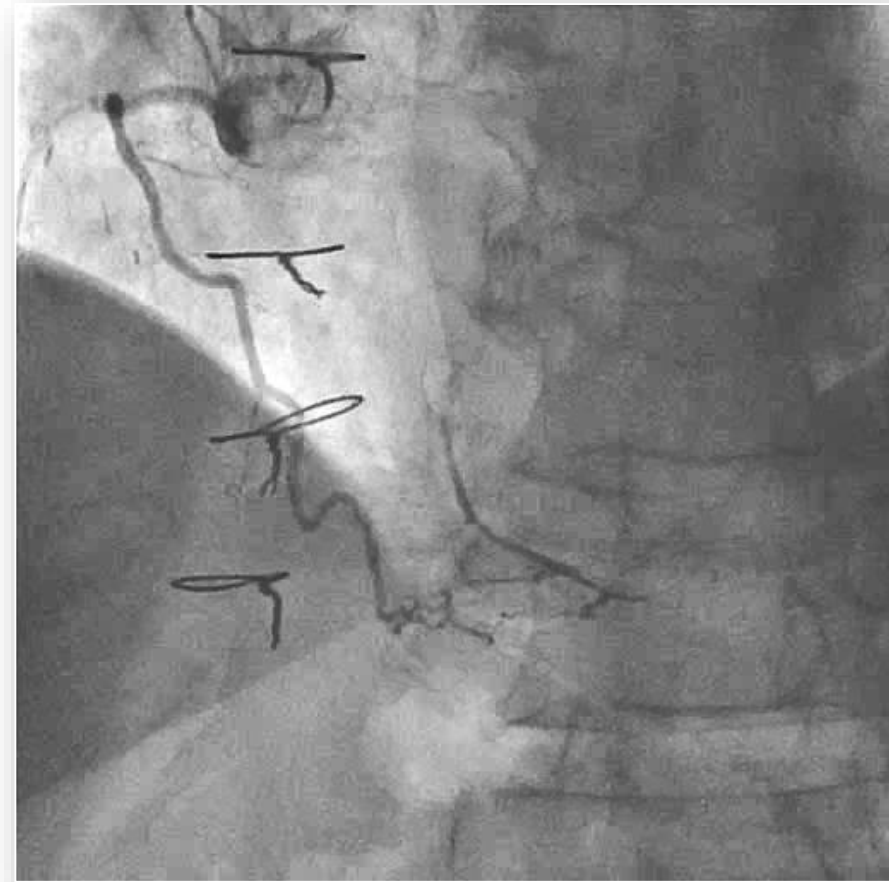
Dicembre 2017: ischemia critica arto inferiore dx: bypass femoro-femorale in crossover + TEA femorale sx

FOLLOW UP

- ***Gennaio 2018: ricovero per angina instabile (troponina -)***
- ***Ecocardiogramma: invariato rispetto ai precedenti***

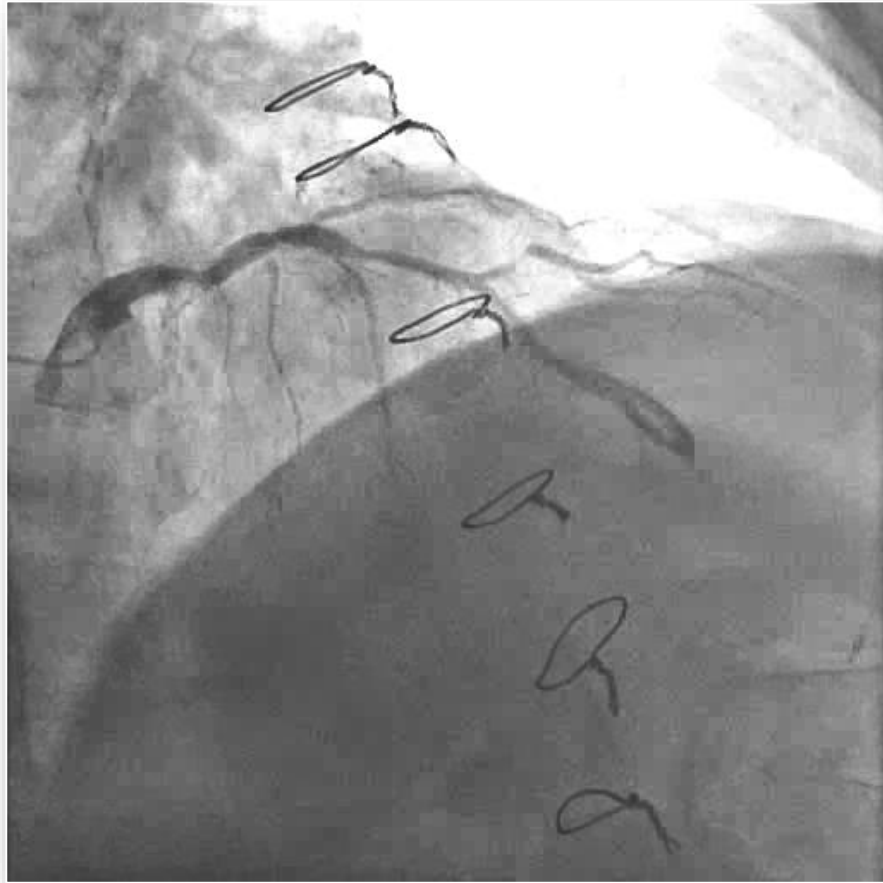


ANGIO



PROGRESSIONE DI MALATTIA DEL CIRCOLO NATIVO

ANGIO

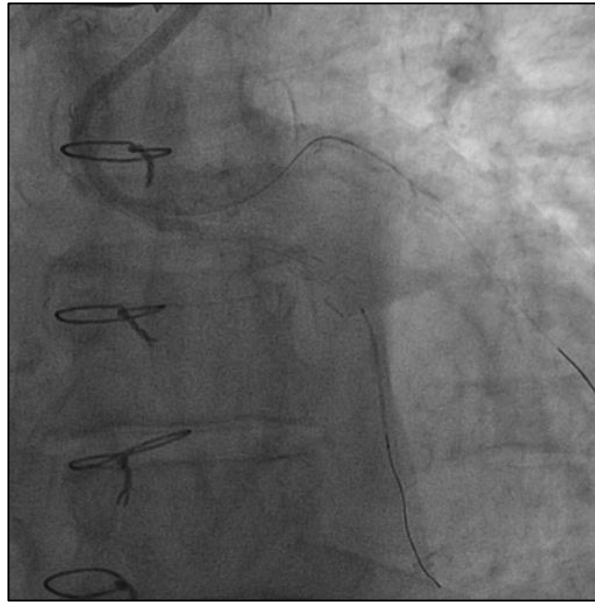


Gradiente trans stenotico: 10 mm Hg

PTCA SU IVA



Pallone 2.0x20 mm

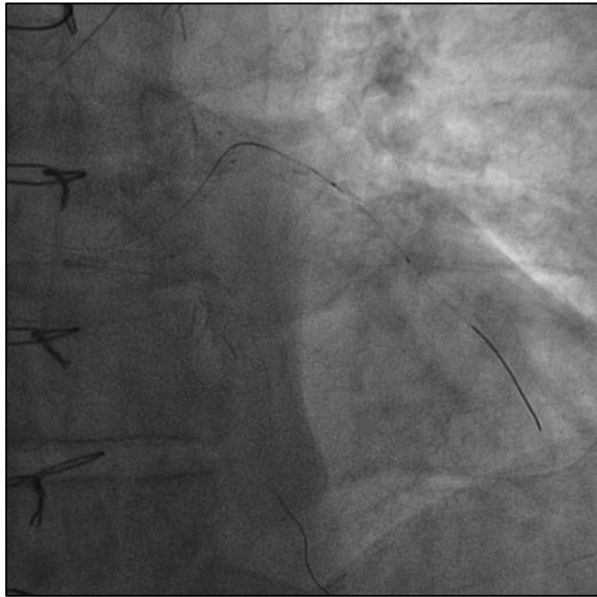


DES 3.0x26 mm



Pallone NC 3.0x20 mm

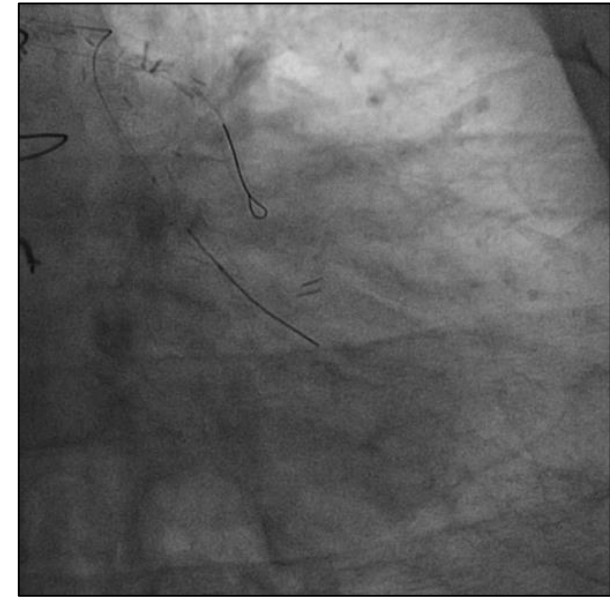
PTCA SU DIAGONALE



Pallone 2.0x20 mm

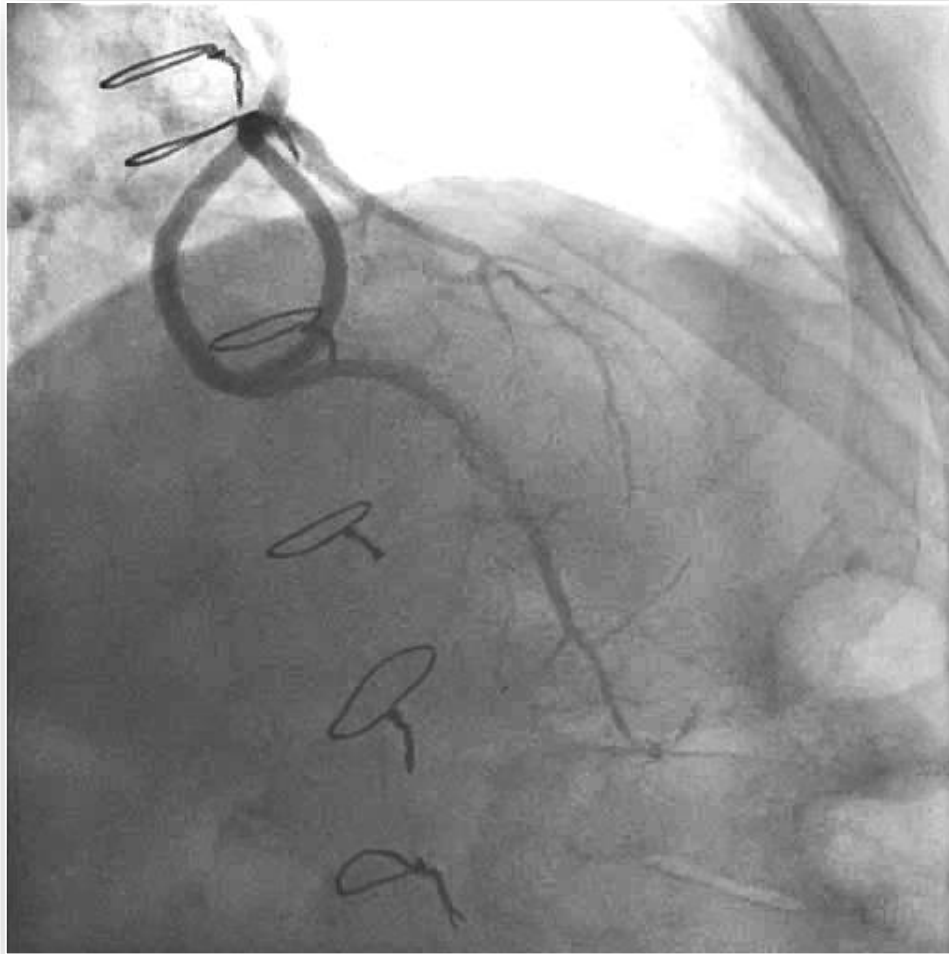


DES 3.0x22 mm



Pallone NC 3.0x20 mm

ANGIO - CONTROLLO



TERAPIA ALLA DIMISSIONE

- ***ASA 100 mg***
- ***Clopidogrel 75 mg***
- ***Amiodarone 200 mg***
- ***Ranolazina 750 mg x 2***
- ***Ramipril 5 mg***
- ***Furosemide 25 mg***
- ***Simvastatina/Ezetimibe 40/10 mg***
- ***Lansoprazolo 30mg***
- ***Allopurinolo 300 mg***

FOLLOW UP

- ***Controllo clinico settembre 2018***
- ***Residua claudicatio classe II sec. Fontaine***
- ***Asintomatico per angina, dispnea, cardiopalmo***
- ***Ecocardiogramma: Fevsx 55%, stenosi aortica con AVA 1,3 cm²***
- ***Terapia: invariata (indicata sospensione del Clopidogrel a gennaio 2019)***

COMPASS study population

Definition of CAD

- **Previous MI**
- OR**
- **Stable angina or unstable angina with documented multi-vessel CAD, >50% stenosis in at least 2 major coronary arteries on coronary angiography, or positive stress test (electrocardiogram) or nuclear perfusion scintigram**
- OR**
- **Multi-vessel percutaneous coronary intervention**
- OR**
- **Multi-vessel coronary artery bypass grafting surgery within 1 week or at least 4 years ago or with recurrent angina or ischaemia at any time following surgery**

Definition of PAD

- **Previous aorto-femoral bypass surgery, limb bypass surgery or percutaneous transluminal angioplasty of the iliac or infrainguinal arteries**
- OR**
- **Previous limb or foot amputation for arterial vascular disease***
- OR**
- **History of intermittent claudication and either an ankle/arm blood pressure ratio ≤ 0.90 or significant peripheral artery stenosis (>50%) documented by angiography or non-invasive testing by duplex ultrasound**
- OR**
- **Asymptomatic carotid artery stenosis# >50% as diagnosed by duplex ultrasound or angiography**

*i.e. excludes trauma; #i.e. no ipsilateral stroke or transient ischaemic attack within 6 months

Clinical study protocol BAY 59-7939/15786

Inclusion and Exclusion Criteria Ensure That Patients Are Chronic CAD and PAD Patients

Key **inclusion** criteria*

- **PAD**
 - **CAD with ≥ 1 of:**
 - **Age ≥ 65 years**
 - **Age < 65 years plus atherosclerosis in ≥ 2 vascular beds or ≥ 2 additional risk factors**
 - **Current smoker**
 - **Diabetes mellitus**
 - **Renal dysfunction (eGFR < 60 ml/min)**
 - **Heart failure**
 - **Non-lacunar ischemic stroke**
- ≥ 1 month ago**

Key **exclusion** criteria‡

- **Stroke ≤ 1 month or any haemorrhagic or lacunar stroke**
- **Severe HF with known ejection fraction $< 30\%$ or NYHA class III or IV symptoms**
- **Need for dual antiplatelet therapy, other non-aspirin antiplatelet therapy, or oral anticoagulant therapy**
- **eGFR < 15 ml/min**

*Including but not limited to; †any other exclusion criteria in conjunction with the local Product Information and any other contraindication listed in the local labelling for rivaroxaban or the comparator have to be considered

www.clinicaltrials.gov/ct2/show/NCT01776424 [accessed 21 Mar 2017]; Bosch J et al, Can J Cardiol 2017;33:1027–1035

PAD population: Independent predictors of MALE

	N	MALE, n (%)	Univariable HR (95% CI)	p-value	Multivariable HR (95% CI)	p-value
Intermittent Claudication Fontaine 3 or 4 Classification	234	22 (9.4)	6.07 (3.83–9.62)	<0.0001	4.79 (2.99–7.69)	<0.0001
Prior amputation at baseline	335	26 (7.8)	5.05 (3.28–7.77)	<0.0001	3.77 (2.40–5.93)	<0.0001
History of peripheral revascularization surgery or angioplasty	2045	74 (3.6)	2.89 (2.03–4.10)	<0.0001	2.44 (1.71–3.50)	<0.0001
Current/former smoker	4789	110 (2.3)	1.96 (1.19–23.23)	0.008	1.59 (0.94–2.67)	0.08
Randomization to aspirin arm of trial	2123	56 (2.6)	1.57 (1.11–2.23)	0.01	1.63 (1.15–2.31)	0.006
History of diabetes	2854	69 (2.4)	1.44 (1.02–2.04)	0.038	N/A	N/A
Women	1786	24 (1.3)	0.61 (0.39–0.96)	0.032	0.64 (0.40–1.01)	0.06
History of CAD	4145	68 (1.6)	0.55 (0.39–0.78)	0.0007	0.71 (0.49–1.02)	0.06

PAD population: MACE and MALE outcomes

Pre-specified outcomes in patients with PAD

	Rivaroxaban 2.5 mg bid + aspirin n (%*)	Aspirin n (%*)	HR	HR (95% CI)	p-value
CV death, stroke, MI (MACE)	126 (5.1)	174 (6.9)	0.72		<0.005
Acute limb ischaemia or chronic limb ischaemia (MALE)	30 (1.2)	56 (2.2)	0.54		0.005
Major amputation	5 (0.2)	17 (0.7)	0.30		0.01
MACE, MALE or major amputation	157 (6.3)	225 (9.0)	0.69		0.0003

0,1 ← Favours rivaroxaban 2.5 mg bid + aspirin Favours aspirin alone → 10

THANK YOU !!

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