

**Interventional Cardiac Catheterization  
in  
Congenital Heart Diseases (II)**

**Difetto Interatriale**

**Forame Ovale Pervio**

# Chiusura di Difetto Interatriale

## Indicazioni

- Difetto Interatriale Ostium Secundum
- Sintomi
- Segni di sovraccarico di volume delle sezioni dx (*livello I:B*)
- Pregressa embolia paradossa (*livello IIa/B*)

# Caratteristiche anatomiche INDISPENSABILI per l'approccio transcatetere

- Difetto tipo OS
- Adeguati margini peri-orifiziali
- Adeguata distanza da VCS, VCI, VVPP, seno coronarico, valvole A-V
- Adeguato rapporto difetto/setto totale (dimensioni del SIA > della protesi scelta)

- DIA "semplice"

- \* centrale

- \* dimensioni <50% del setto interatriale

- \* buoni margini peri-orifiziali

- DIA "complesso"

- \* >2 cm con scarso margine peri-orifiziale

- \* setto interatriale aneurismatico

- \* setto interatriale multifenestrato

## *Limiti*

- Anatomia del SIA (aneurisma, multifenestrato, ecc)
- Dimensioni e sede del difetto e rapporto DIA/setto ( $<0.60$ )
- Margini peri-orifiziali adeguati ( $>5$  mm)
- Discrepanza atrio sx/protesi

10:29:27 am

3V2c 51Hz

H3.5MHz 110mm

CUORE

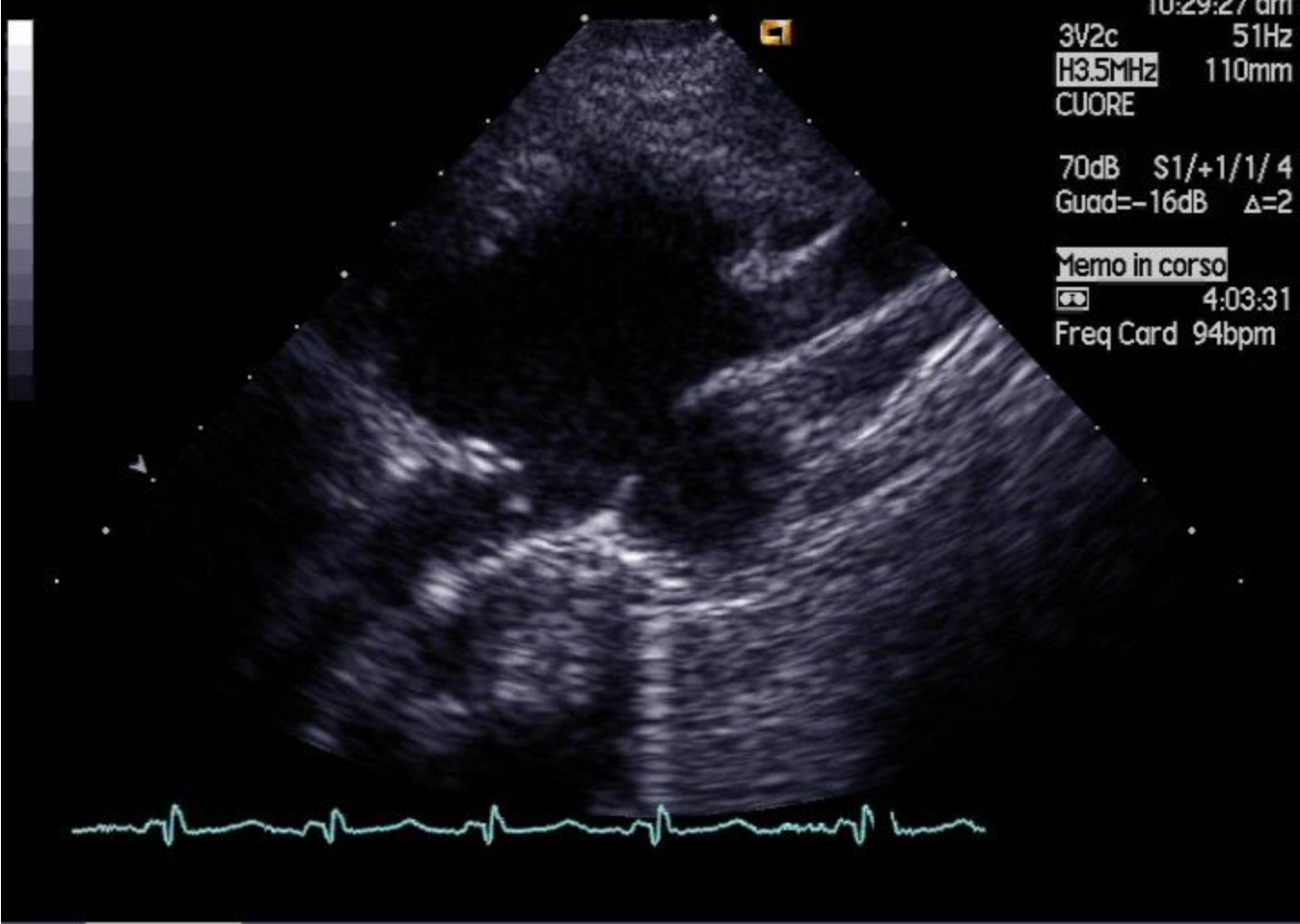
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Guad=-16dB Δ=2

Memo in corso

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Freq Card 94bpm

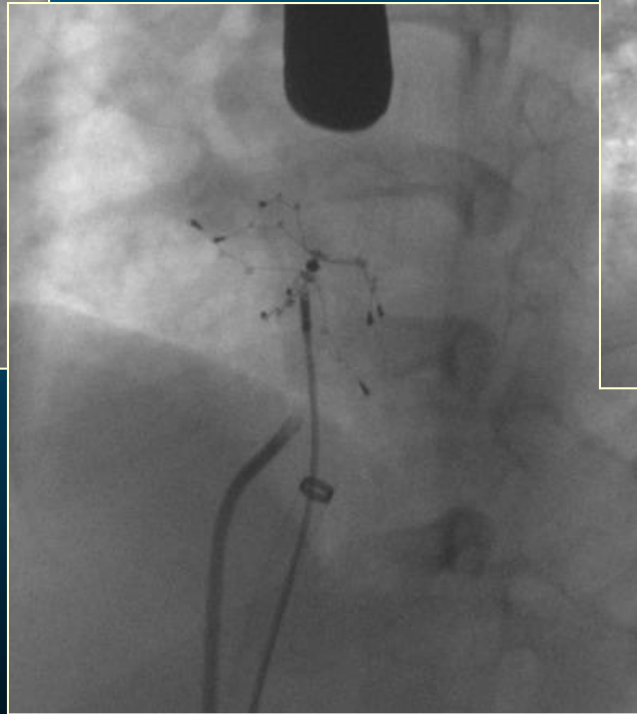
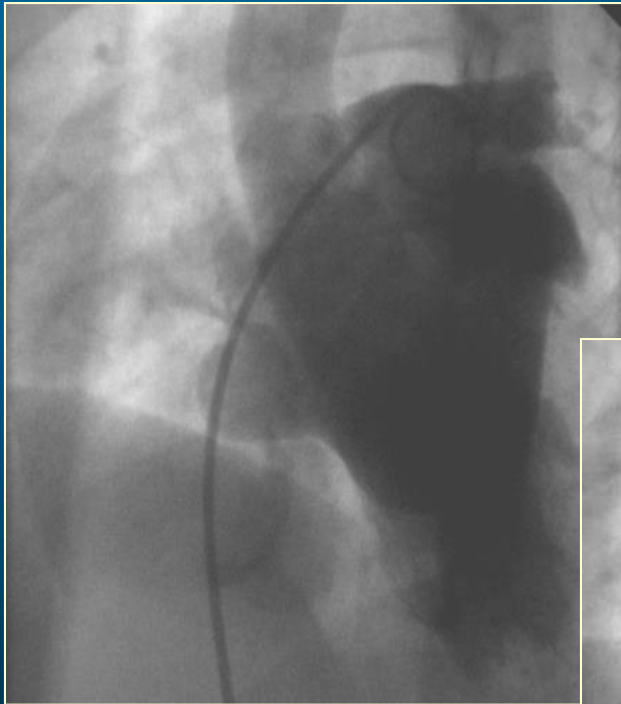


1-COOLBLUE

Grey Scale



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TIS: 0.8

T. PAZ: 37.0C

4.4MHZ

T621B

T. TEE <37.0C

59

DE OTT. AC

0.015T. .091 cm

ELAB 8/0/E/18/A

CARDIOL. PEDIATRI

CA 2^UNIV. NAPOLI

TEE

SAPORITO



59

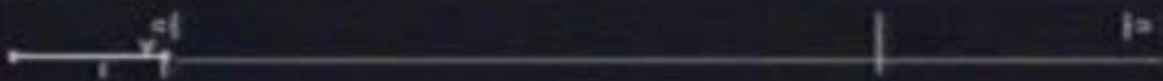
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GUAD. 50

COMP. 65

12CH

16HZ



# *Chiusura di Forame Ovale Pervio*

## *Indicazioni*

- L'applicazione clinica della chiusura transcatetere ha preceduto la precisa delineazione delle indicazioni al trattamento basata su studi clinici randomizzati-controllati

- Interesse scientifico-assistenziale nella prevenzione di patologie cardiovascolari o neurologiche ad elevata prevalenza nella popolazione generale ed altamente invalidanti
- Interesse economico da parte di industrie produttrici di protesi occludenti che ha indotto all'applicazione clinica utilizzando la via dell'Humanitarian Device Exemption

An iceberg floating in the ocean. The tip of the iceberg is above the water surface, and the much larger part is submerged below. The word 'FOP' is written in large yellow letters across the submerged part of the iceberg. A yellow box highlights the text 'TIA/ictus cerebrale' above the tip of the iceberg.

TIA/ictus cerebrale

Ischemia cerebrale  
silente

IMA a coronarie integre

Embolia paradossa  
periferica

Emicrania non familiare

Demenza Vascolare

Malattia da  
decompressione nei  
subacquei

Sindrome  
ortodeoxia/platipnea

Desaturazione idiopatica

Morbo di Alzheimer

Altro ???

- Il potenziale mercato mondiale delle protesi per chiusura del FOP è di  $\approx 2$  miliardi di dollari/anno
- Ciascuna procedura ha un costo medio di  $\approx 10000$  dollari

MI: 0.4

T. PAZ: 37.0C

T6210

T. TEE: 37.0C

13 LUG 85

11:12:23

ELAB 0/0/E/S3

CARDIOL. PEDIATRI

CA 2^UNIV. NAPOLI

TEE

QUARANTA

MADDALENA

00964.12

GUAD 52

COMP 66

9CM

71HZ



## **AHA/ASA Guideline**

### **Guidelines for Prevention of Stroke in Patients With Ischemic Stroke or Transient Ischemic Attack**

**A Statement for Healthcare Professionals From the American Heart Association/American Stroke Association Council on Stroke**

- 1. For patients with an ischemic stroke or TIA and a PFO, antiplatelet therapy is reasonable to prevent a recurrent event (Class IIa, Level of Evidence B). Warfarin is reasonable for high-risk patients who have other indications for oral anticoagulation such as those with an underlying hypercoagulable state or evidence of venous thrombosis (Class IIa, Level of Evidence C).**

**2. Insufficient data exist to make a recommendation about PFO closure in patients with a first stroke and a PFO. PFO closure may be considered for patients with recurrent cryptogenic stroke despite optimal medical therapy (Class IIb, Level of Evidence C) (Table 7).**

# Indicazioni "OFF-LABEL" in corso di valutazione in studi

## RANZOMIZZATI-CONTROLLATI

- Prevenzione primaria in subacquei con FOP a rischio di eventi clinici durante decompressione
- Prevenzione primaria o secondaria di una presunta embolia paradossa coronarica o periferica attraverso il FOP

- Prevenzione secondaria dell'ictus criptogenetico da presunta embolia paradossa attraverso il FOP in soggetti con controindicazione alla terapia anti-coagulante o come alternativa alla terapia medica o alla chiusura chirurgica

- Prevenzione secondaria dell'embolia paradossa cerebrale, coronarica o sistemica in soggetti con FOP e condizioni di ipercoagulabilità

- Prevenzione secondaria dell'embolia adiposa cerebrale post-traumatica attraverso il FOP

- Trattamento della deossigenazione sistemica da shunt dx-sx a livello del FOP in assenza di ipertensione polmonare (ad es. sindrome platipnea-ortodeossia, infarto ventricolare dx)
- Trattamento dell'emicrania non familiare con o senza aura

# **SPREAD**

Stroke Prevention And Educational Awareness Diffusion

## **IV Edizione**

### **Ictus cerebrale:**

**linee guida italiane di prevenzione e trattamento**

**Milano 2005**

- Nei pazienti con ictus ischemico o TIA e forame ovale pervio (FOP), esenti da trombosi venose profonde e al primo evento trombo-embolico è indicato il trattamento con ASA

- Nel caso di ictus o TIA e:
- FOP associato ad ASI e primo evento
  - FOP isolato e TVP o diatesi trombofilica
  - FOP isolato, con shunt di grosse dimensioni, e multipli eventi ischemici

*Dopo avere escluso altre eziologie è indicato scegliere, sulla base del rapporto rischio/beneficio, tra terapia anticoagulante (INR 2-3) e chiusura transcatetere*

➤ Nel caso di ictus o TIA e:

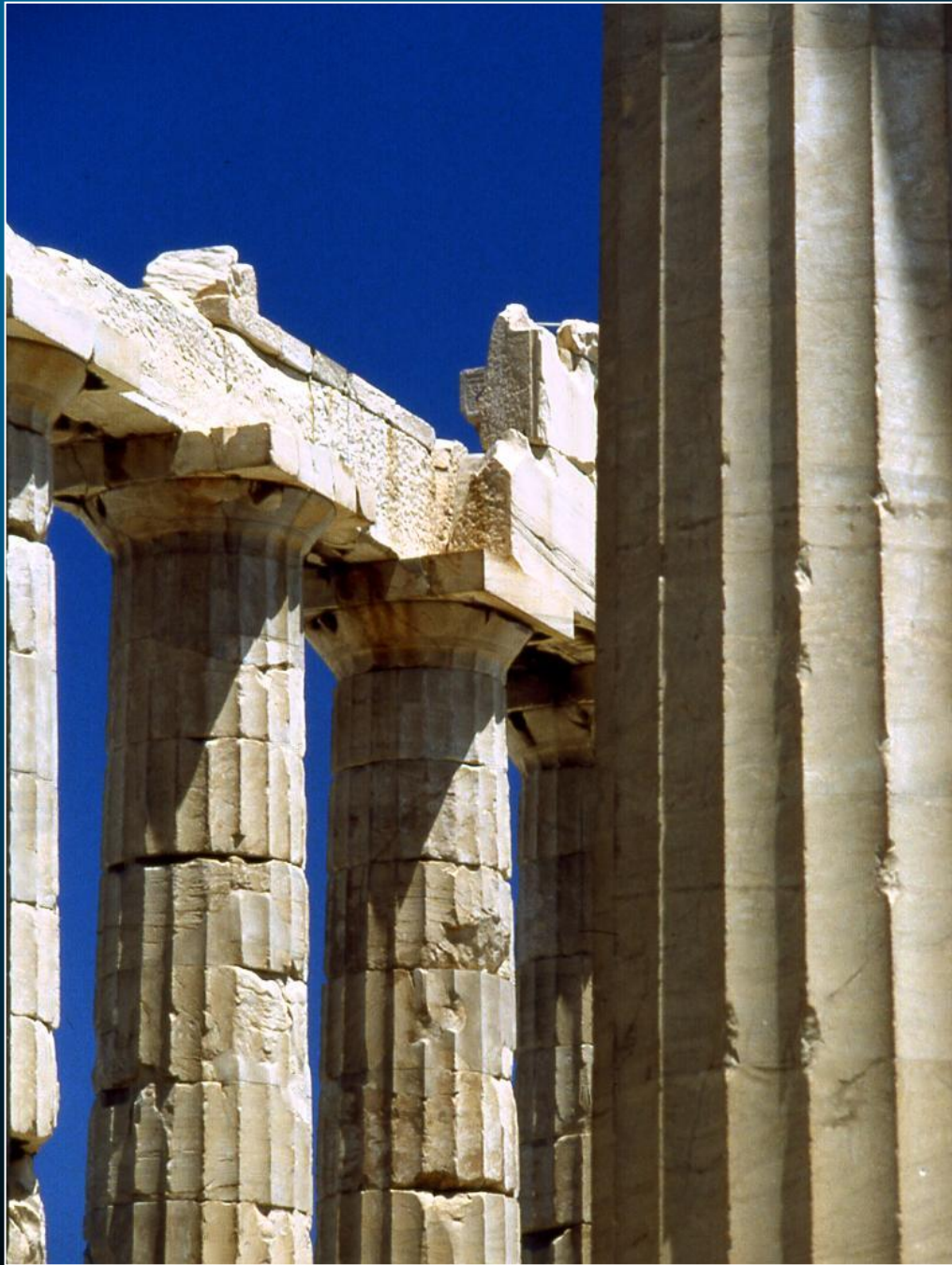
- FOP associato ad ASI al primo evento ma con TVP o diatesi trombofilica e controindicazioni alla terapia anticoagulante

- FOP con sintomatologia recidivante nonostante terapia anticoagulante

*Dopo avere escluso altre eziologie è indicata la chiusura transcateretere e, in caso di fallimento, la chiusura chirurgica*

## Problemi da risolvere

- Prevenzione "primaria" in soggetti asintomatici con FOP+/-ASI e multipli focolai "gliotici" cerebrali
- Prevenzione "primaria" in soggetti con FOP +/- ASI ad alto profilo di rischio candidati a procedure chirurgiche ad alto rischio di embolia paradossa
- Prevenzione secondaria in soggetti con FOP +/- ASI e pregressa embolia polmonare/sistemica periferica



**Dotto Arterioso Pervio**

# Chiusura PDA/malformazioni vascolari

## Indicazioni

- Sintomi da scompenso cardiaco
- Segni di sovraccarico di volume (*livello I:B*)
- Prevenzione dell'endocardite batterica o dell'embolia paradossa (*livello IIb:B*)

## *Limiti*

- Et /peso del paziente (>1 mese e/o >4 kg)
- Caratteristiche anatomiche locali (fistole AV cerebrali/coronariche)
- Potenzialmente tutte trattabili !!!



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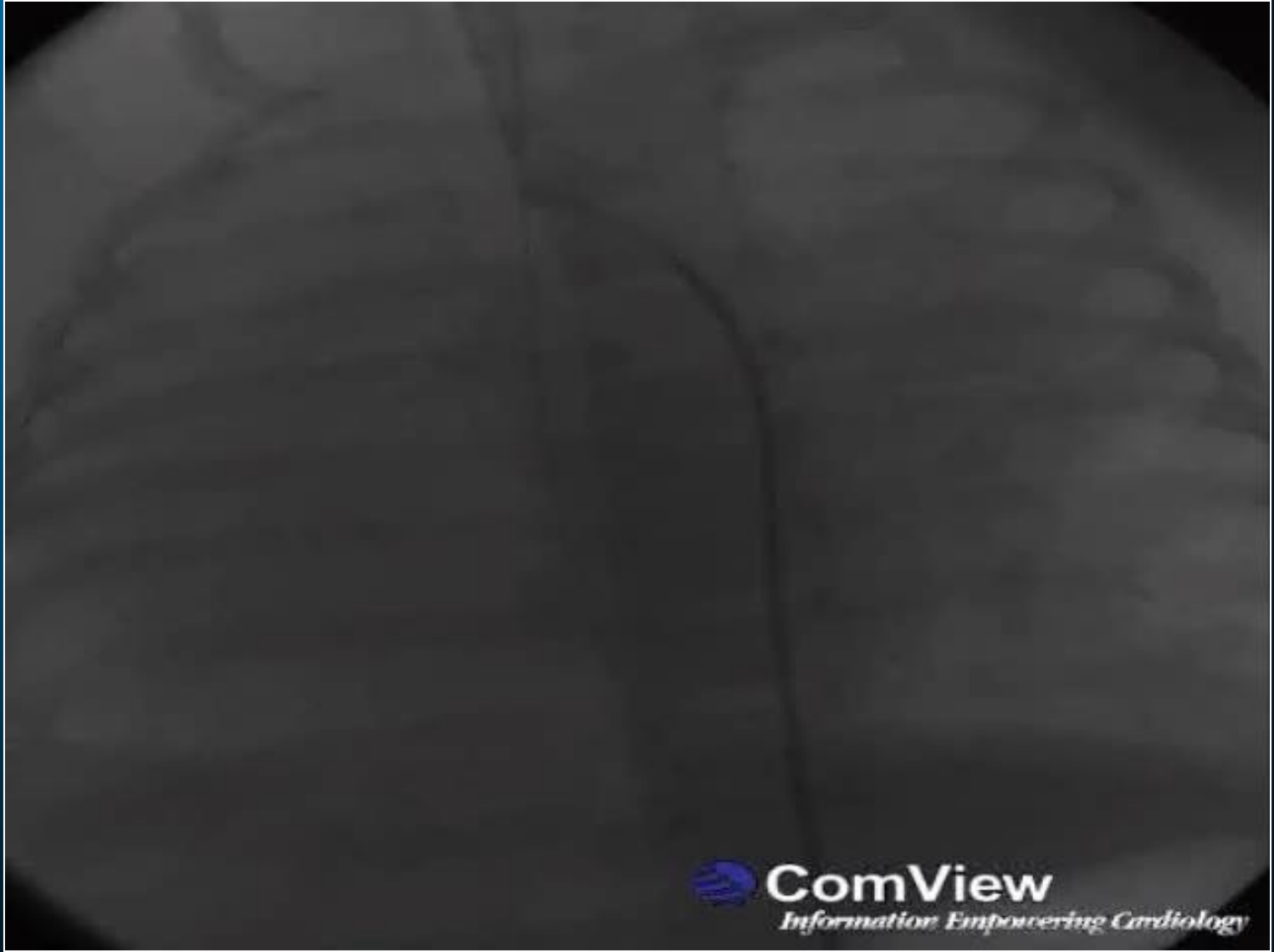
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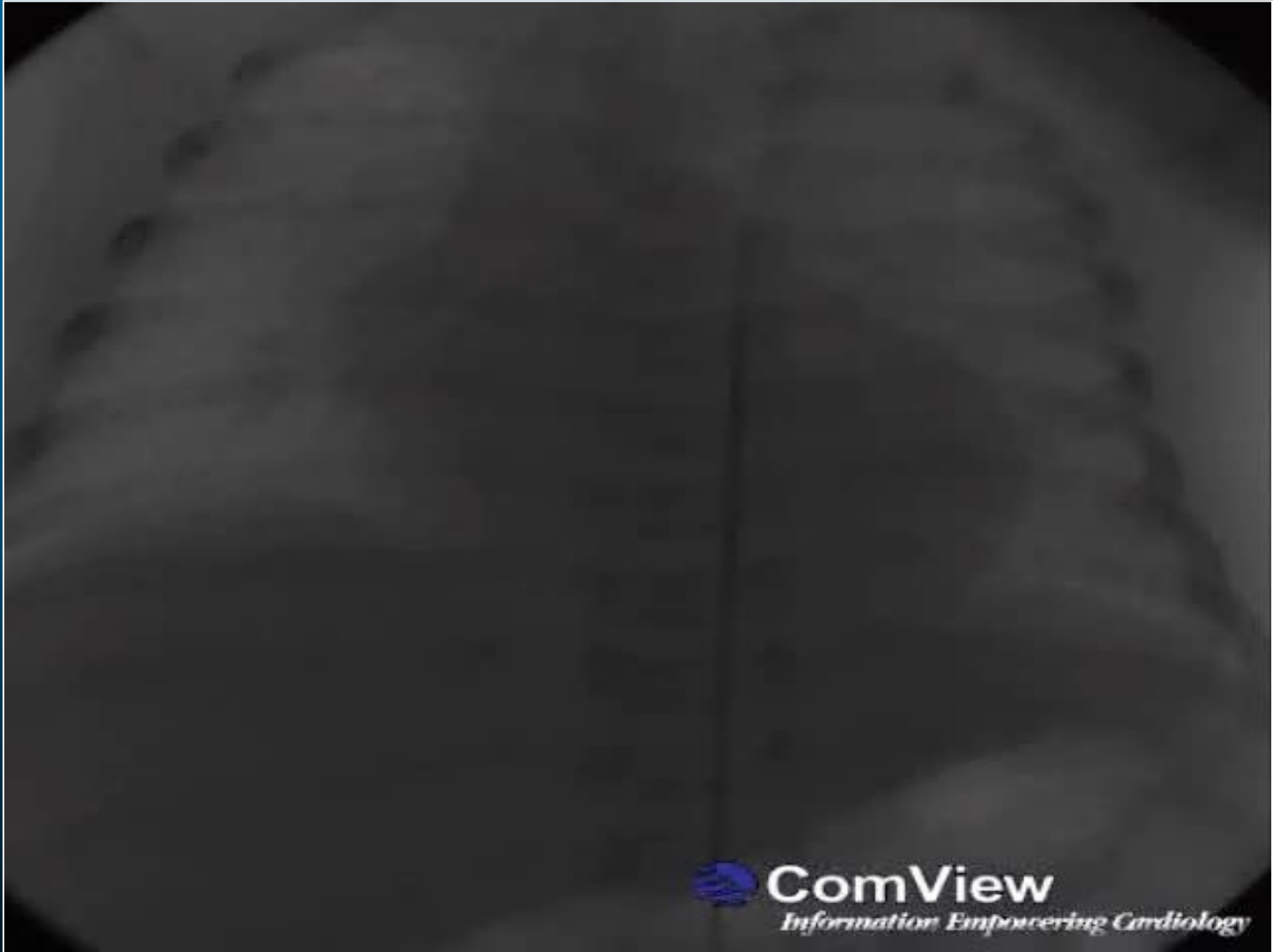
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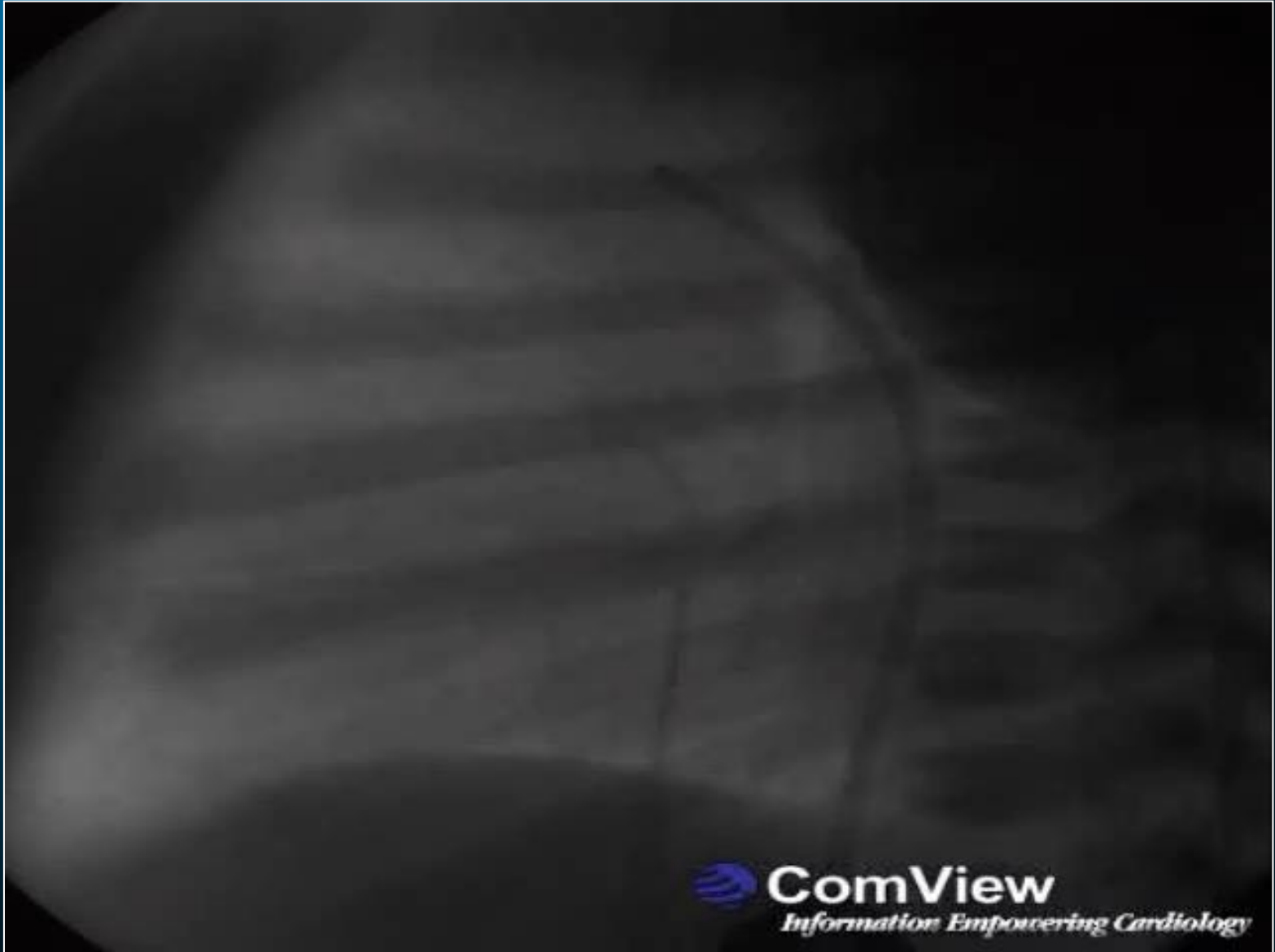
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Trattamento di  
cardiopatie congenite  
"chirurgiche"

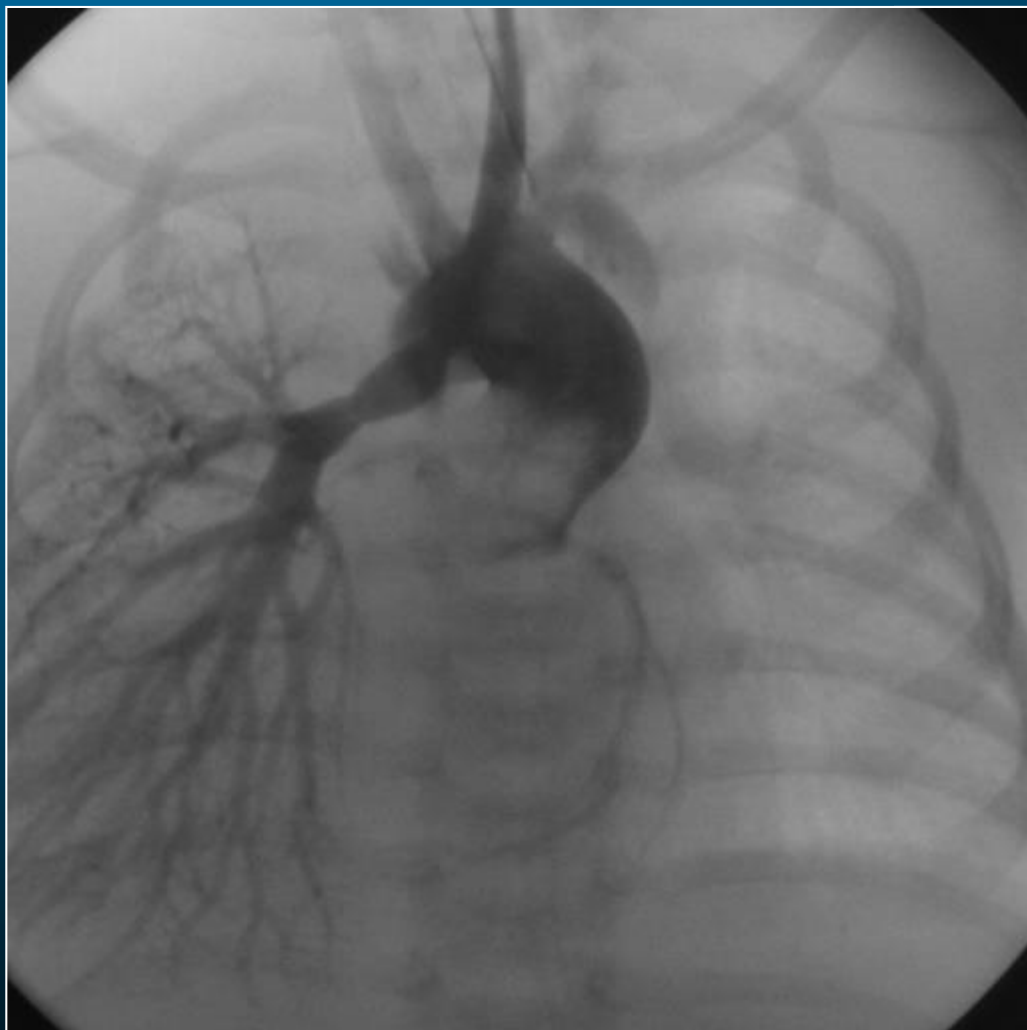
- Shunt sistemico-polmonare
- Difetto interventricolare (nativo, post-chirurgico o post-IMA)
- Lesioni multiple associate
- Impianto di protesi valvolare (polmonare o aortica)
- Altro

- Per tutte queste cardiopatie le indicazioni sono quelle "chirurgiche" ed i limiti sono fissati dalle caratteristiche anatomo-funzionali del singolo paziente e dall'abilità, spregiudicatezza, inventiva e fortuna dell'operatore

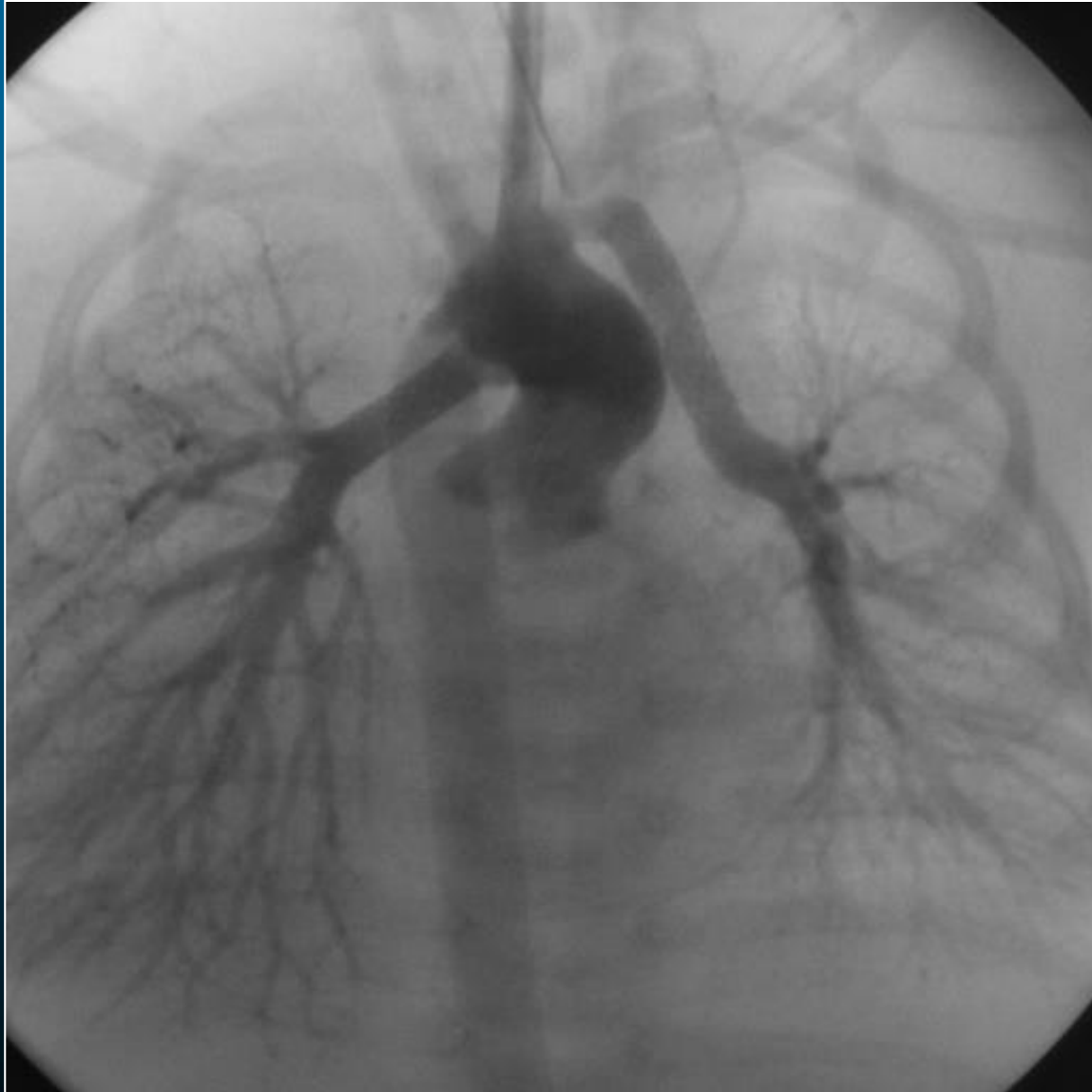


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# *Emodinamica Interventistica nelle Cardiopatie Congenite*



# Chiusura di Difetto Interventricolare

## Indicazione

### ➤ Congenito

- Sovraccarico di volume
- $QP/QS > 1.5$
- Profilassi dell'endocardite

(livello *IIb:B*)

### ➤ Post-IMA

- Difetto cronico (>2-3 settimane)

## *Limiti*

- Et /peso del paziente (>4 anni e/o >20 kg)
- Anatomia del difetto (dimensioni, sede, aneurisma multi-fenestrato, ecc)
- Rapporto con le strutture anatomiche circostanti (valvola Ao, sistema di conduzione, ecc.)



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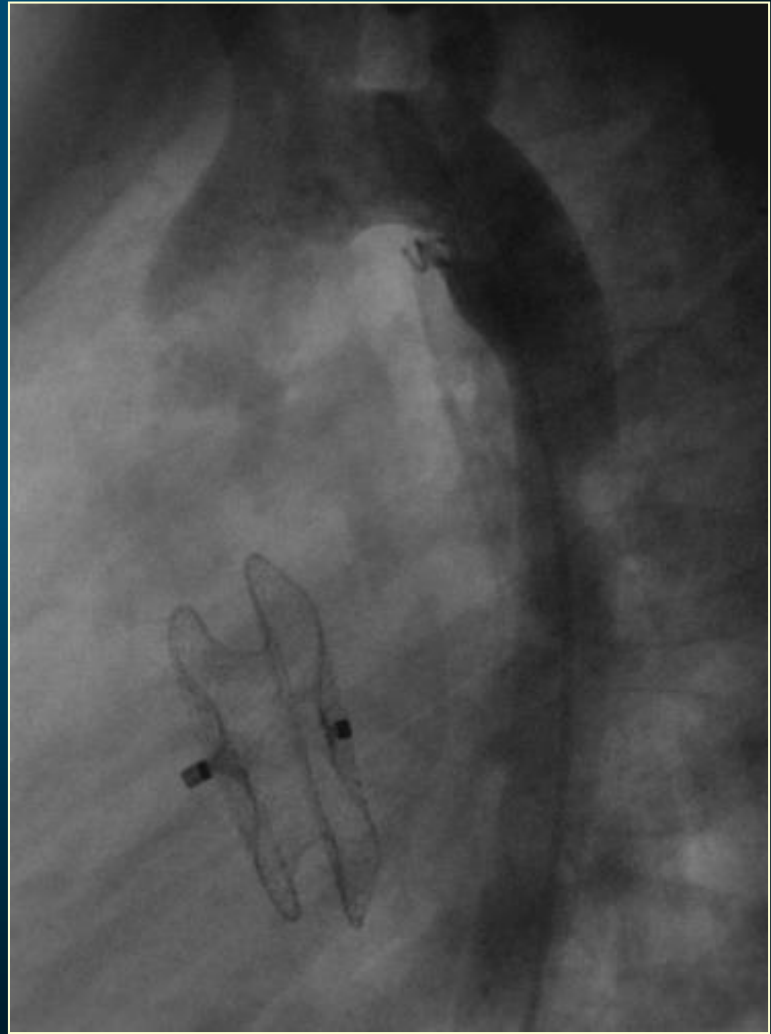
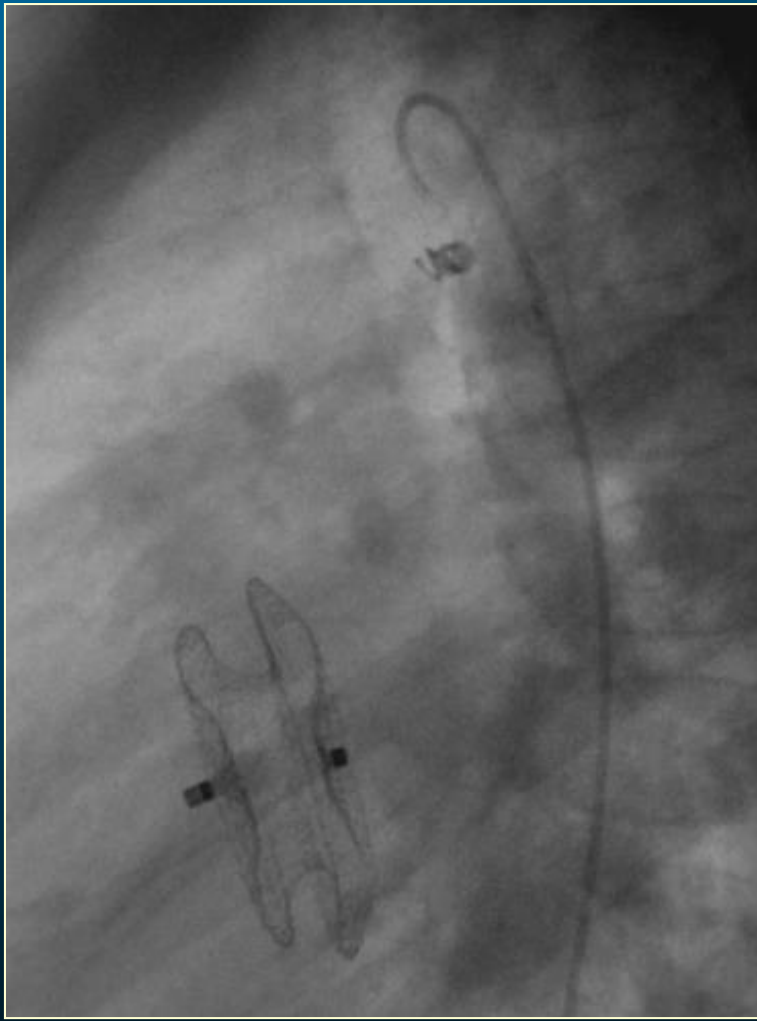
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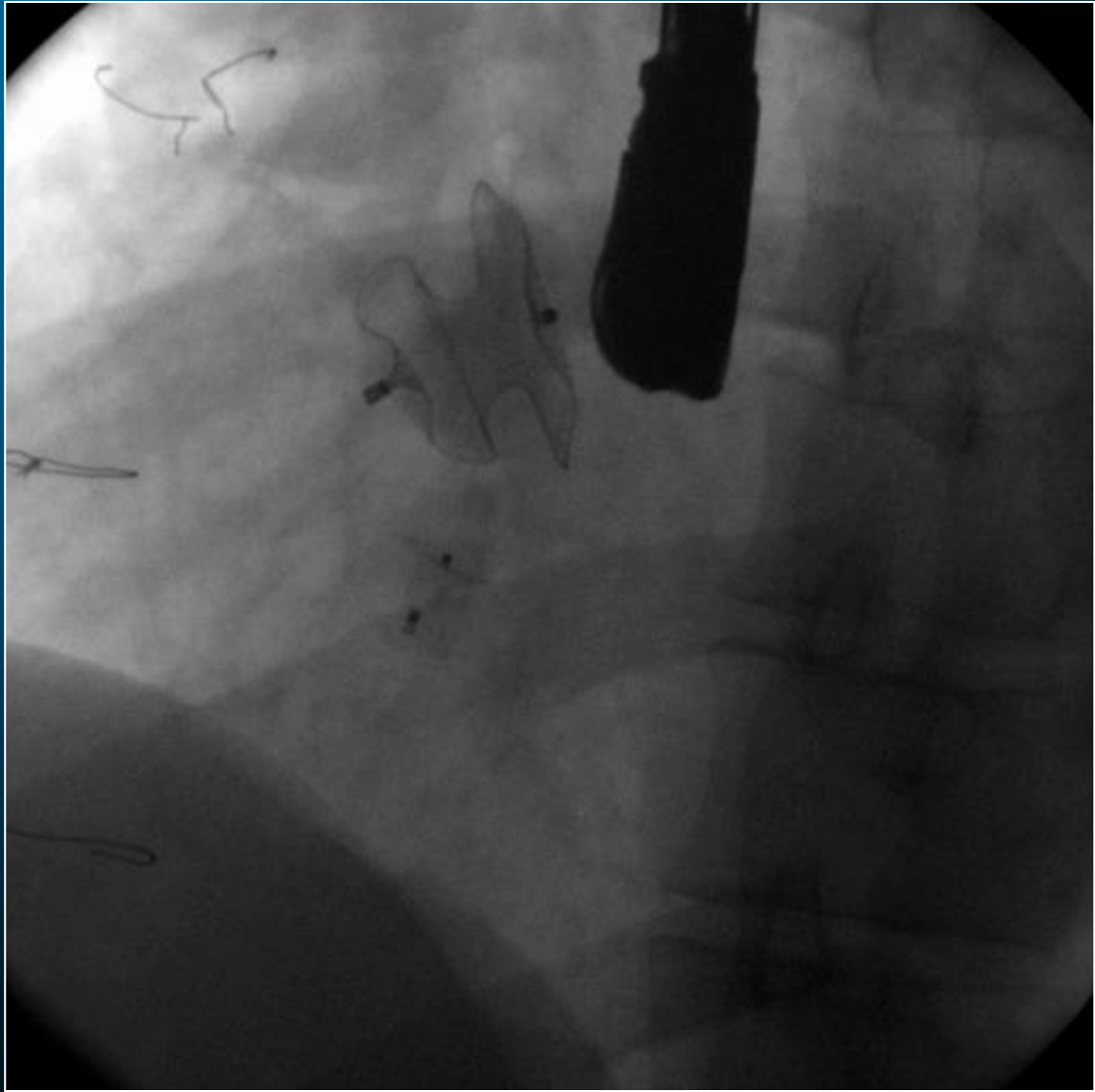
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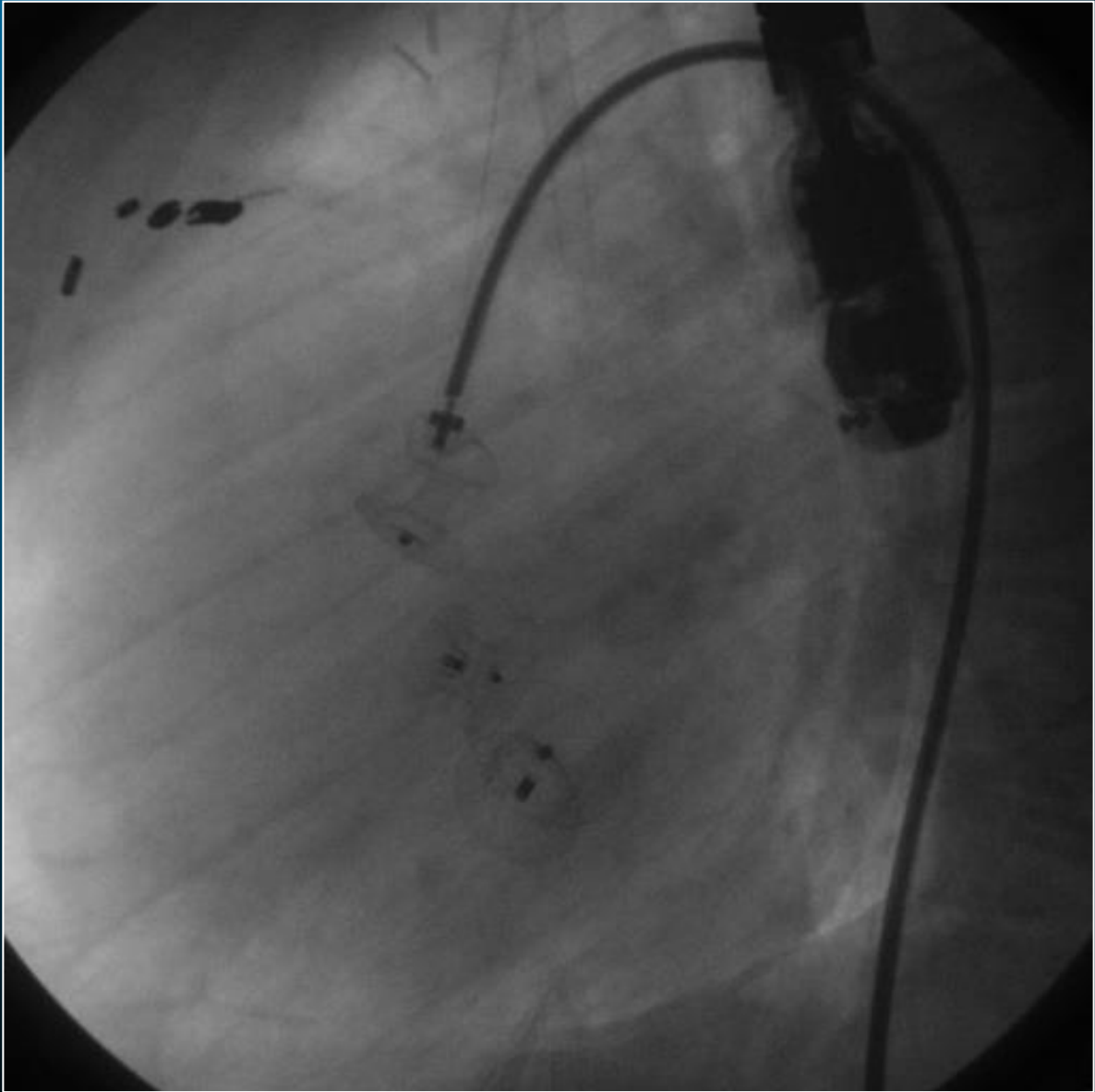


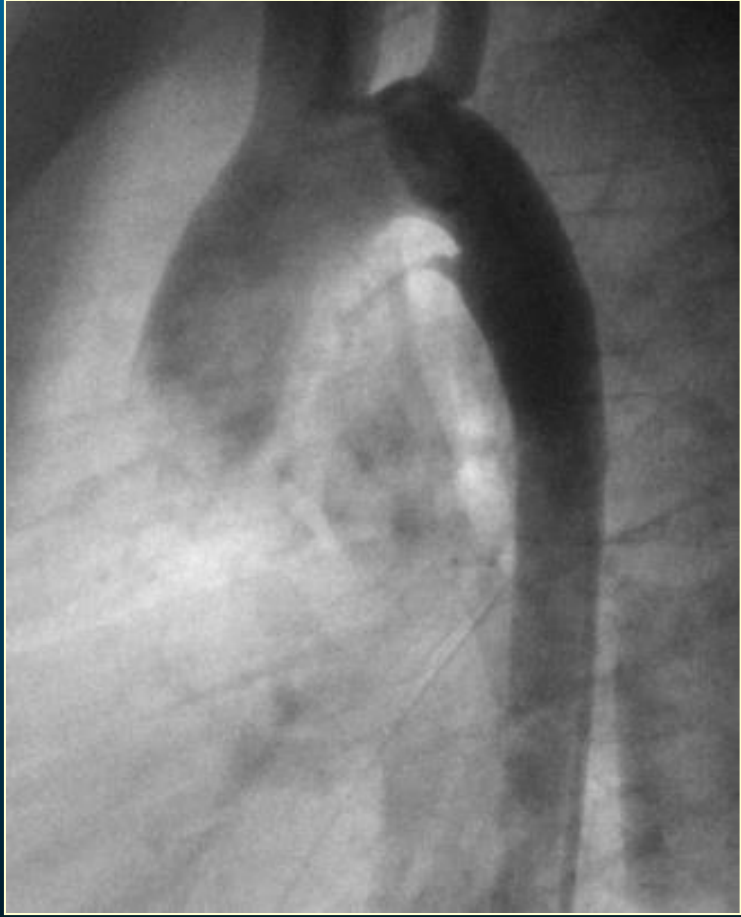
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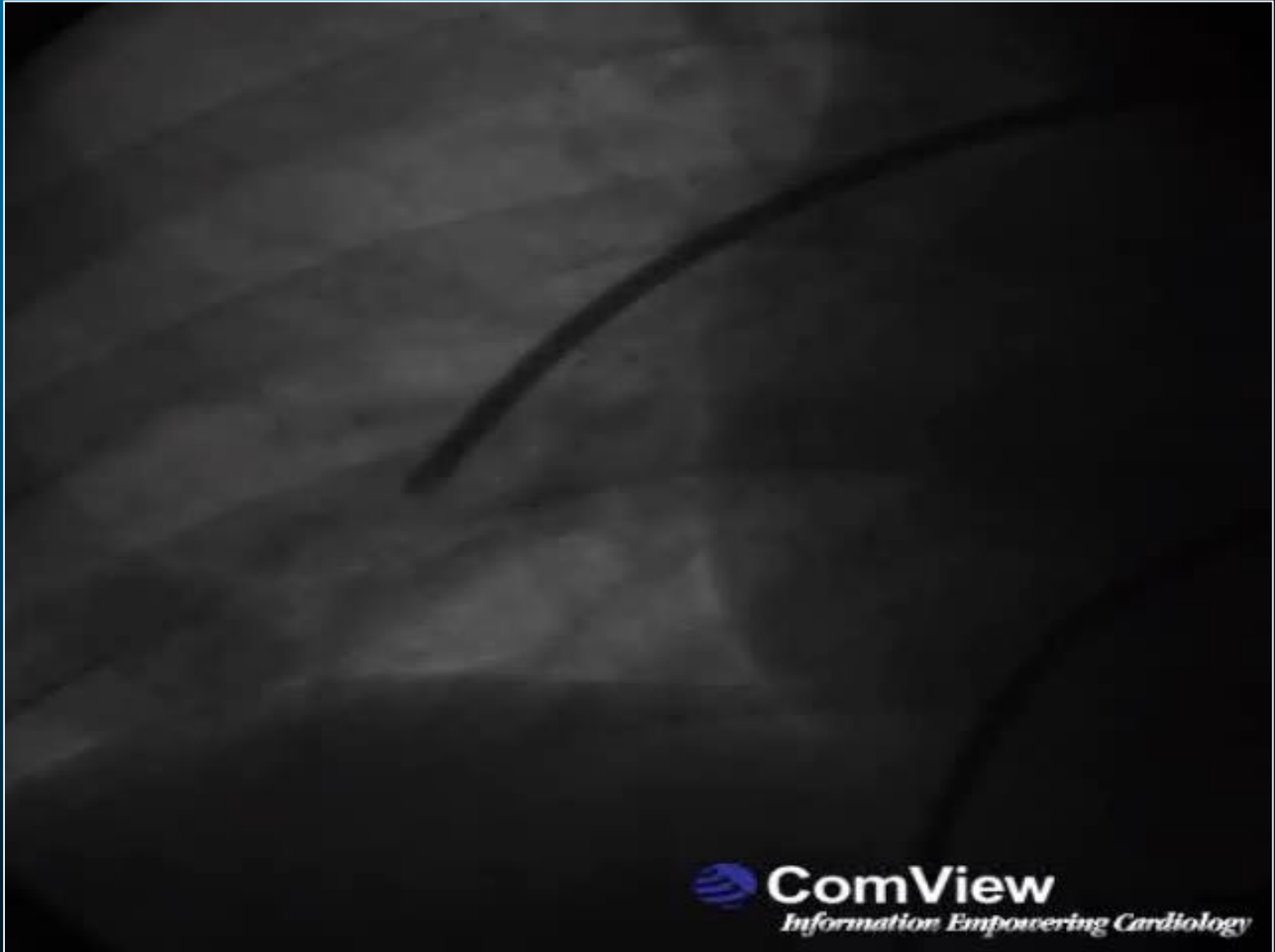




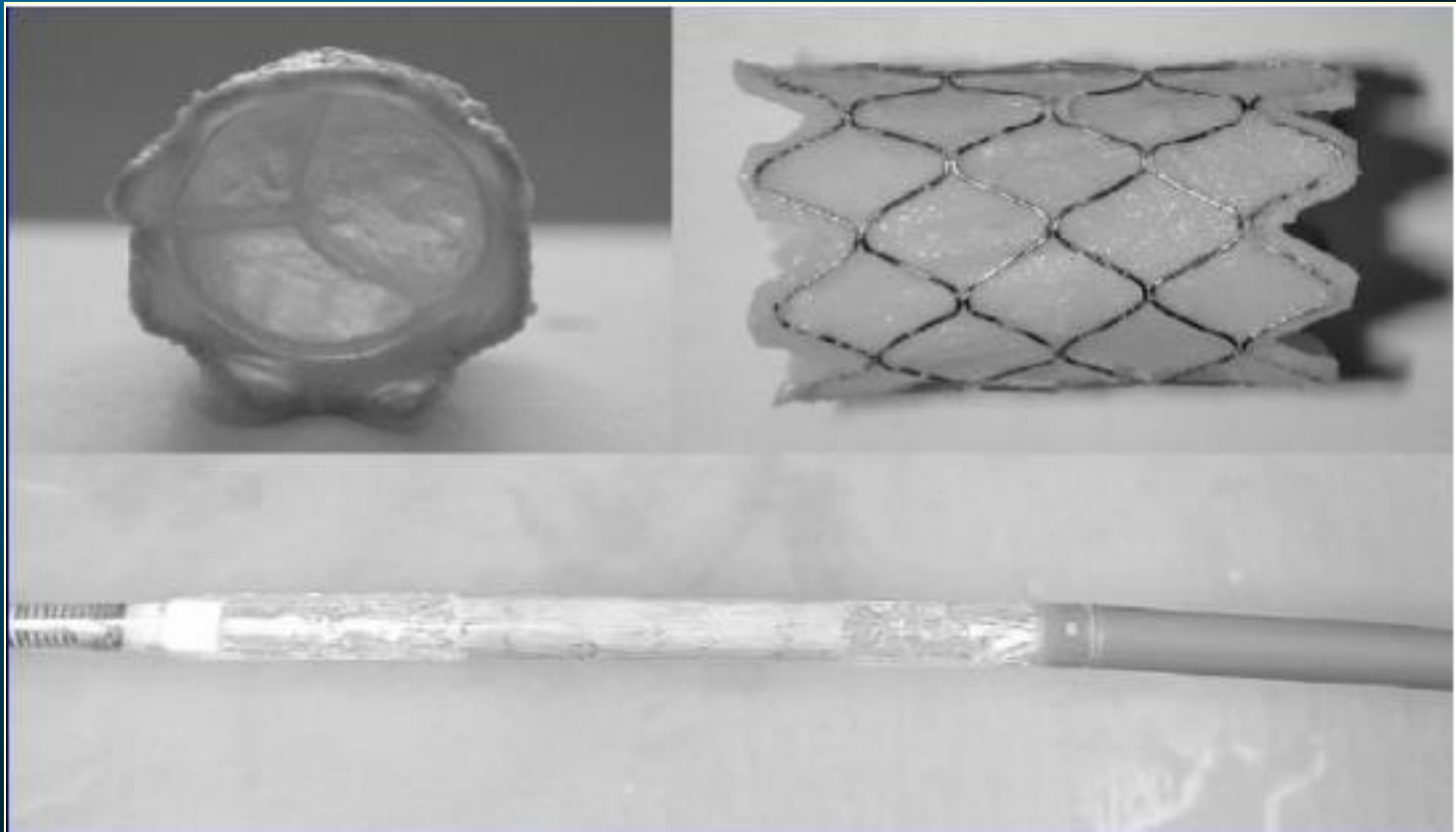


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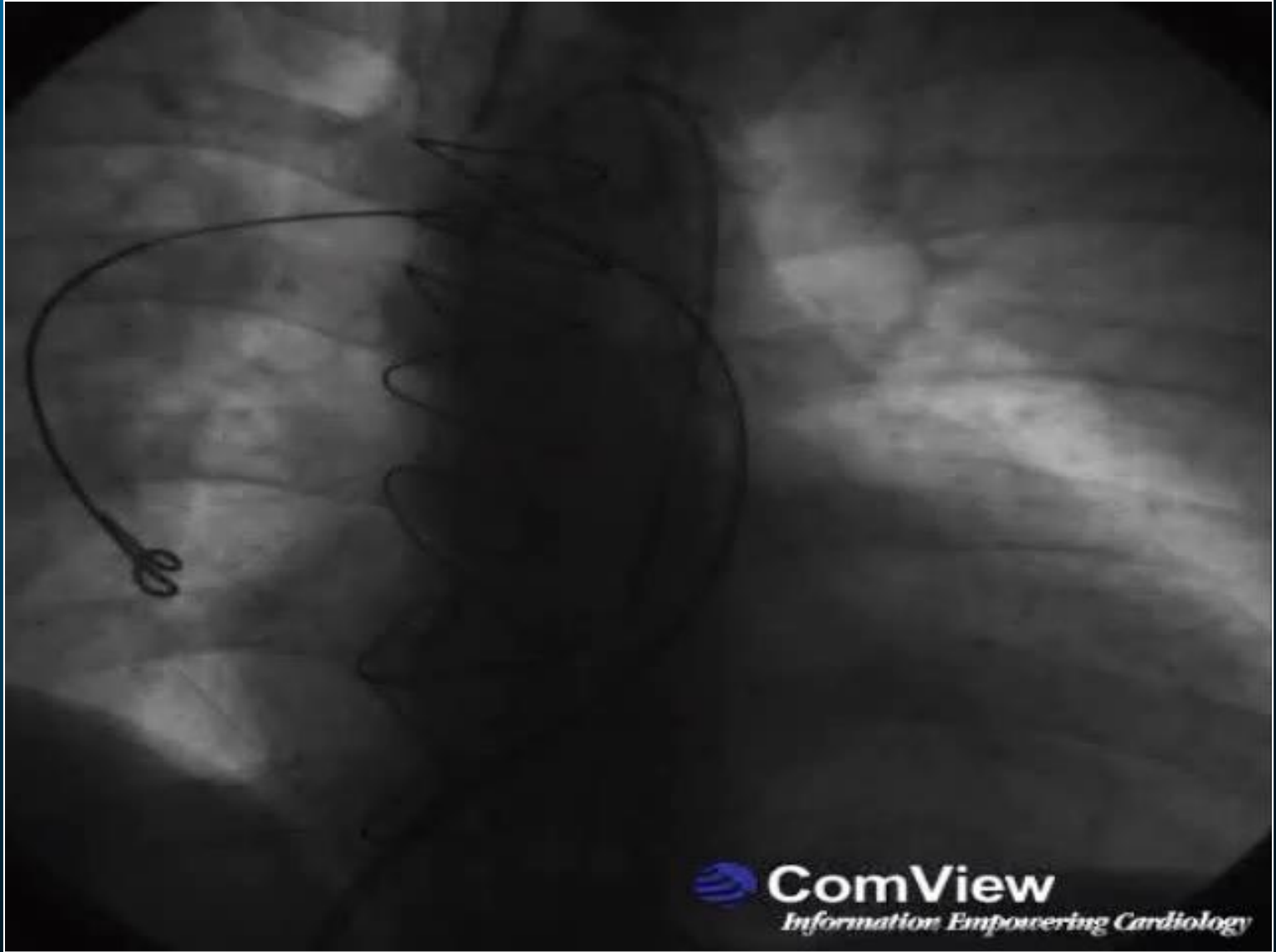
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*Bonhoeffer P, et al. Lancet 2000*





Approccio combinato  
("ibrido") alle  
cardiopatie congenite  
"chirurgiche"

➤ **Hybrid Interventional/Surgical Approach** is defined any combined catheter-based and surgical intervention performed in one setting or in a planned, close sequential fashion

➤ It typically incorporates an open approach to delivery a device

- Procedura "preparatoria" alla chirurgia correttiva
- Procedura di "completamento" post-chirurgico
- Approccio "combinato" sequenziale



- Ridurre i rischi della chirurgia correttiva
- Evitare la circolazione extracorporea
- Ridurre i tempi di intervento

# Indications

## ➤ *Clinical*

- low-weight patients (vascular access, patient/material size mismatch, etc)
- co-morbidities (need for major or multiple surgical approaches, etc)
- clinical instability (basal or anticipated during percutaneous procedures)

## ➤ *Anatomical*

- poor vascular access (patient size, previous vascular accesses, etc)
- tortuous vascular/cardiac course to the target lesion
- unusual septal orientation

➤ *Technical*

→ associated lesions requiring surgical repair

→ need for multiple surgical accesses in the same procedure

→ anticipated further surgery (cardiac or extra-cardiac)

# History

- *Bhati BS, et al. Closure of patent ductus arteriosus during open-heart surgery. JTCS, 1972.*
- *Fishberger SB, et al. Congenital heart disease: intraoperative device closure of VSDs. Circulation, 1993*
- *Mendelsohn AM, et al. Intraoperative and percutaneous stenting of congenital pulmonary artery and vein stenosis. Circulation, 1993*
- *Gibbs JL, et al. Stenting of the arterial duct combined with banding of the pulmonary arteries and atrial septectomy or septostomy: a new approach to palliation for the HLHS. Br Heart J 1993*

## Present Domains of Hybrid Therapy

- Muscular VSD closure in low-weight or high-risk patients using per-ventricular or open heart approach and percutaneous devices
- Vascular stent implantation in clinical or anatomical challenging cases through cardiac or vascular surgical exposure

➤ Hypoplastic Left Heart Syndrome palliation or HLHS-like in high-risk neonates destined to Fontan track or as temporary bridge toward biventricular repair

➤ More and more ... based on creativity and concord of the "therapeutic team"

➤ *Current perspectives*

- valve perforation/angioplasty (critical PV stenosis/atresia; PA-VSD; aortic stenosis) in low-weight or critical patients
- off-pump valve replacement
- aortic coarctation angioplasty or stenting in complex cases

→ per-atrial ASD septal closure  
(complex cases in low-weight patients;  
during complex hybrid or conventional  
surgery)

→ peri-membranous VSD closure

→ intra-operative device interventions  
before/during/after “complex” surgical  
procedures

## *Hybrid Approach for per-ventricular MVSD closure: technical notes*

- sternotomic (or mini-thoracotomic or sub-xyphoid) approach
- RV free wall exposure and purse string suture placement opposite to the VSD perpendicular to the septum

→ RV wall needle puncture through the pulse string

→ guide-wire probing the VSD and entry inside the LV

→ vascular sheath entry over the guide-wire

→ device deployment under TEE-guide

➤ *Advantages vs conventional surgery*

→ minimal incision (potentially sub-xyphoid)

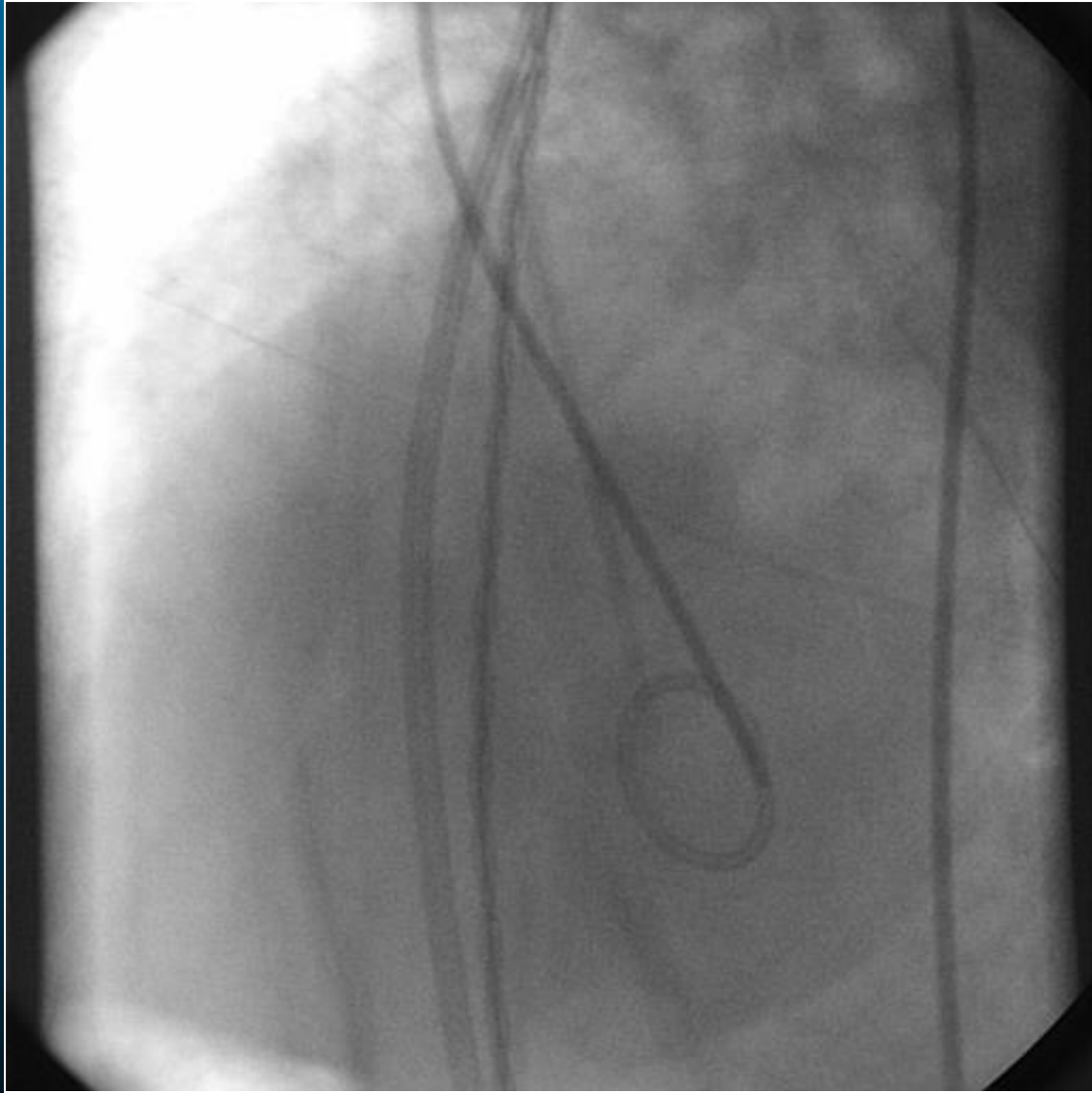
→ “off-pump” intervention or decrease by-pass time

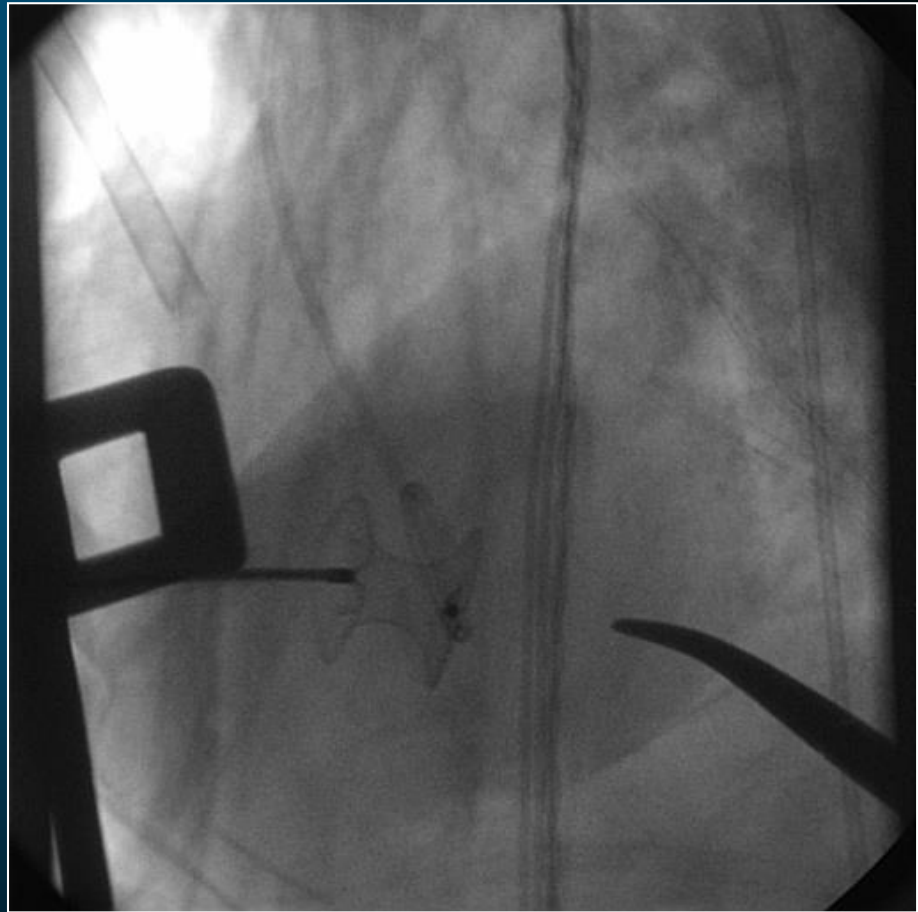
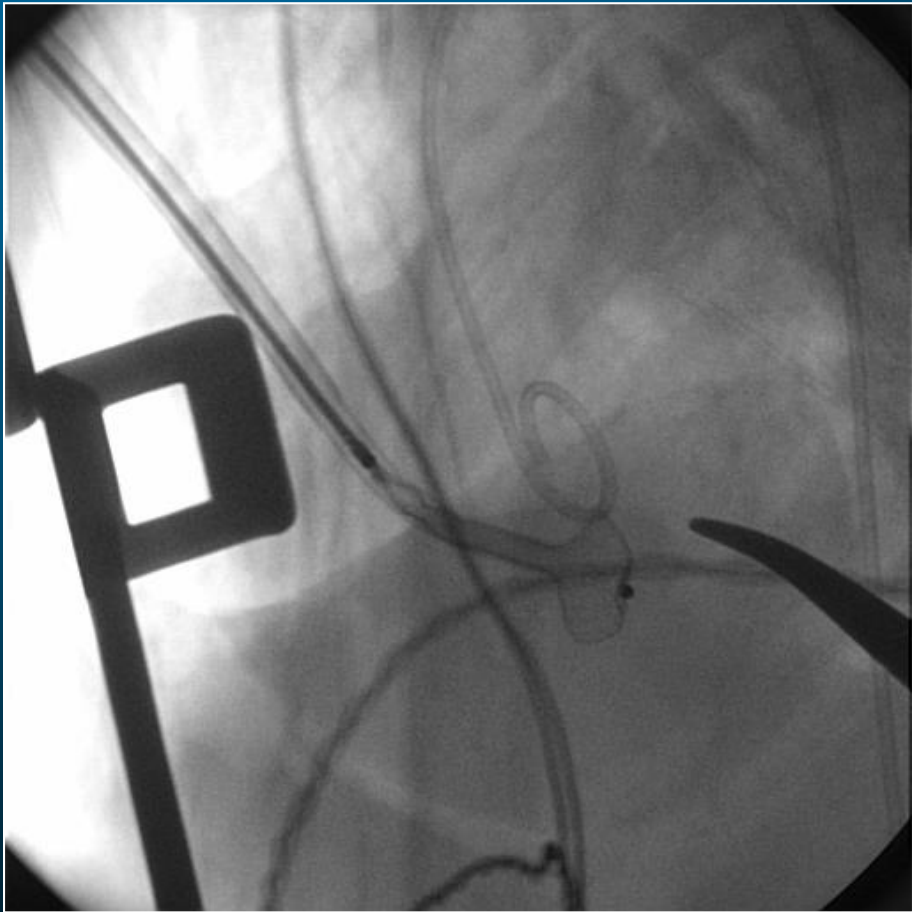
→ easier approach to apical MVSD (avoiding ventricular incision and transection of the moderator band or other muscle debriding procedures)

→ real-time evaluation of the results by intra-operative TEE/angiography

## ➤ *Advantages vs conventional cath*

- free access to the ventricular septum regardless of patient size/VSD location
- straighter course to the target lesion (critical in unstable patients)
- no limitation for large delivery sheaths or unusual septal orientation
- better management of complications (device embolization, AV valve malfunction, etc)
- possibility of rescue (VSD) surgery or concomitant surgical repair





➤ *Intra-operative pulmonary vessel stenting: technical notes*

→ sternotomic or mini-thoracotomic approach

→ vascular exposure

→ purse string suture placement, guide-wire entry and vascular sheath insertion

→ angiographic visualization in multiple views to choose the stent length/diameter

→ guide-wire negotiation of the stenosis

→ stent deployment under direct vision or fluroscopic/angiographic guide

➤ *Advantages vs conventional surgery*

→ “off-pump” intervention or decrease by-pass time

→ easier treatment of distal and/or complex vascular stenoses

→ better structural support to the repaired PA (either vascular wall collapse or external compression)

→ real-time evaluation of the results by intra-operative angiography

## ➤ *Advantages vs conventional cath*

→ free access to circulation regardless anatomic issues

→ straighter course to the target lesion in tortuous vessels

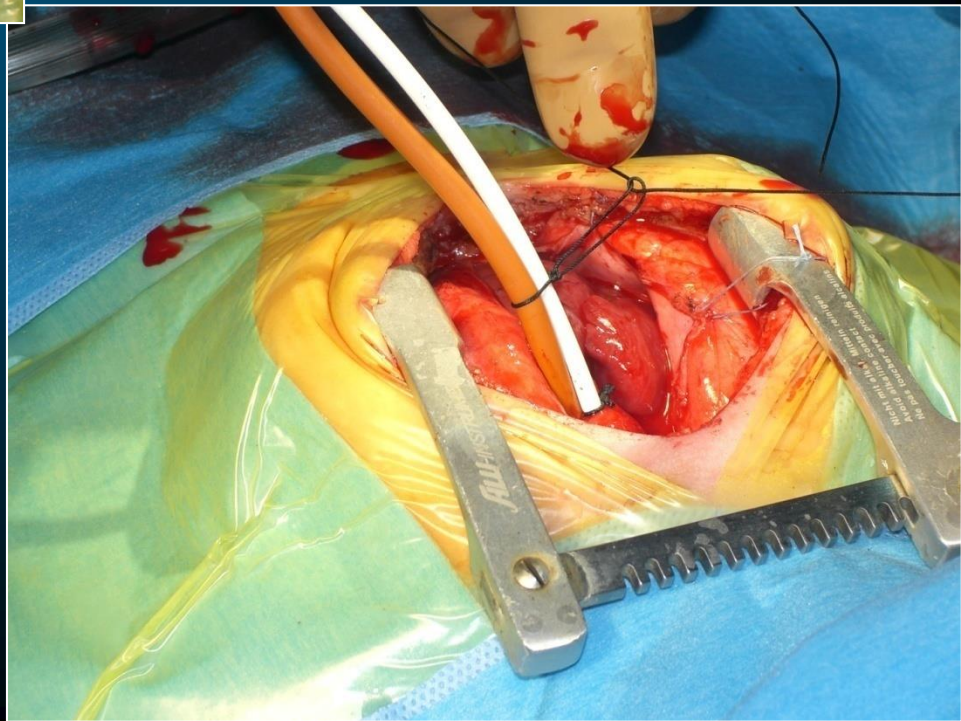
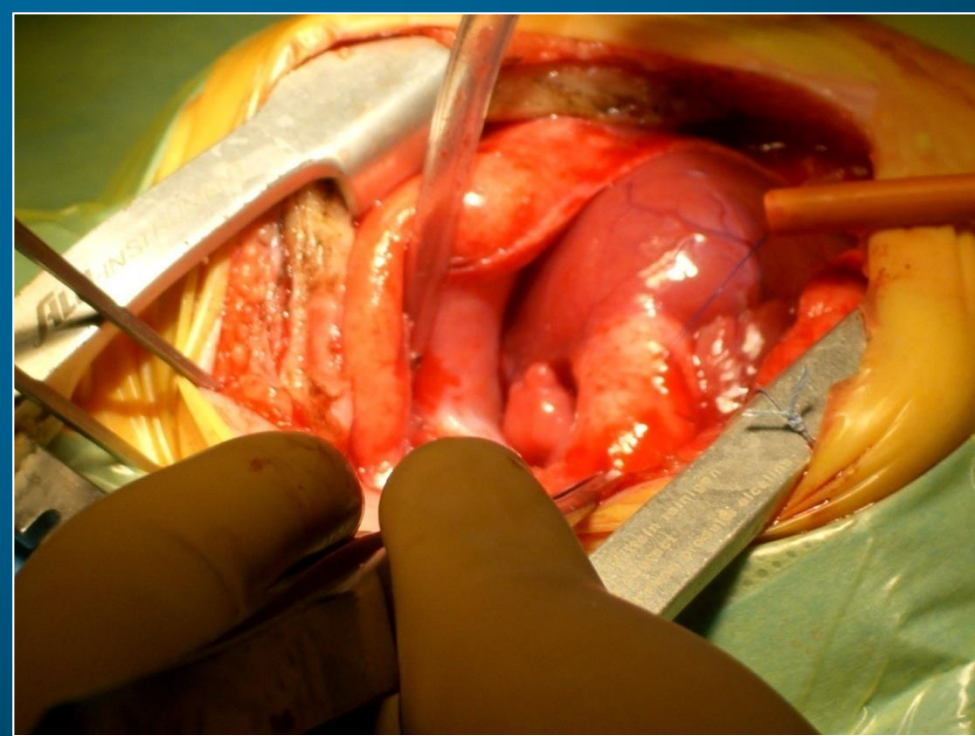
→ no limitation for large delivery sheaths

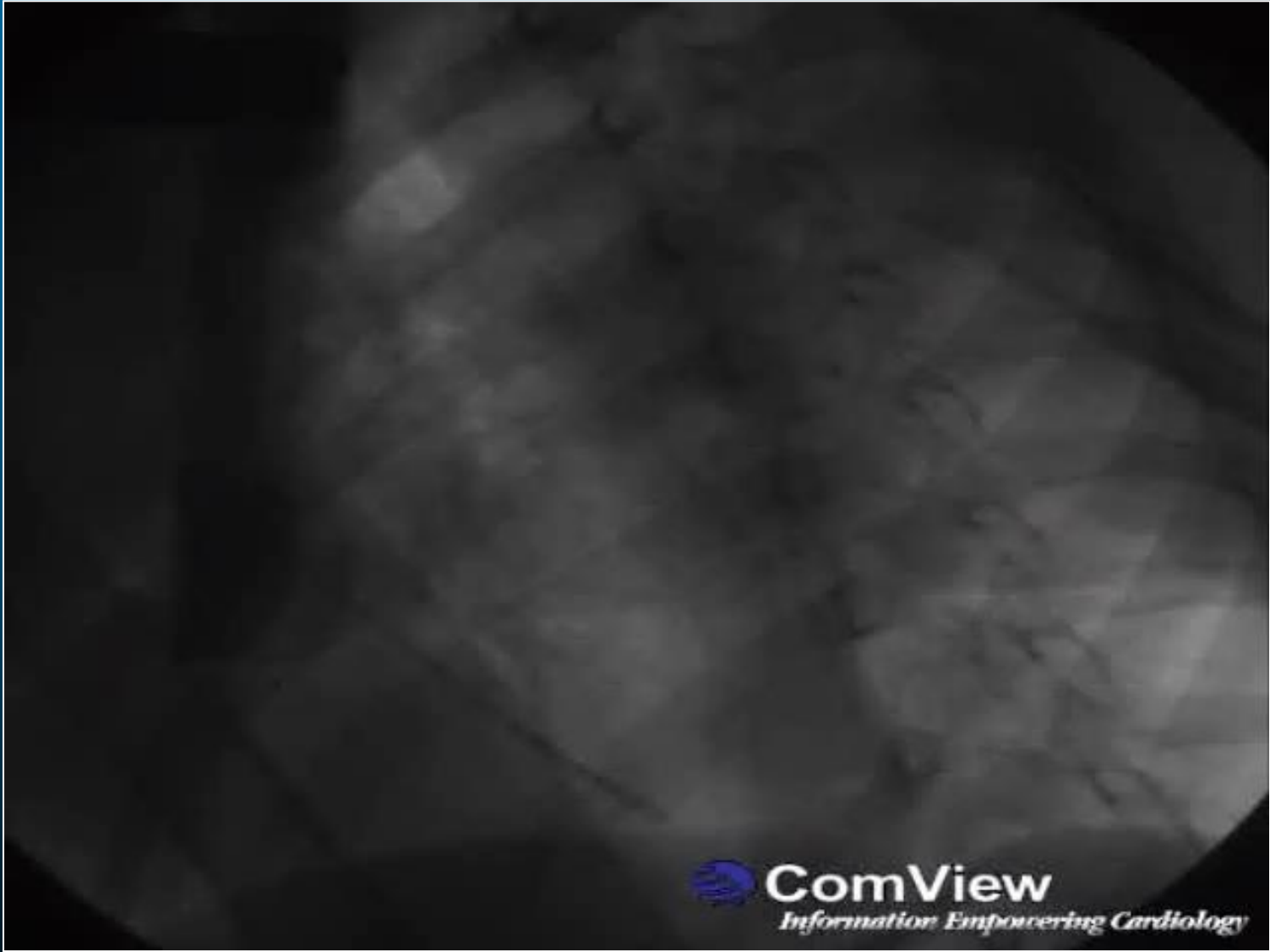
→ use of stents of "adult" diameter (or potentially re-expandable to "adult" size)

→ better management of complications (vessel tear, balloon rupture, stent migration, etc)

→ possibility of concomitant surgery







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## *Conclusioni*

- Grazie al miglioramento dei materiali ed all'affinamento delle tecniche procedurali, l'emodinamica interventistica pone ormai come valida alternativa al trattamento chirurgico di molte cardiopatie congenite sia ad esordio neonatale che infantile
- In alcuni casi, inoltre, essa costituisce una efficace opzione terapeutica palliativa per stabilizzare il neonato prima dell'intervento chirurgico correttivo oppure, utilizzando tecniche "ibride" volte ad eseguire una correzione chirurgica meno complessa e/o a minor rischio