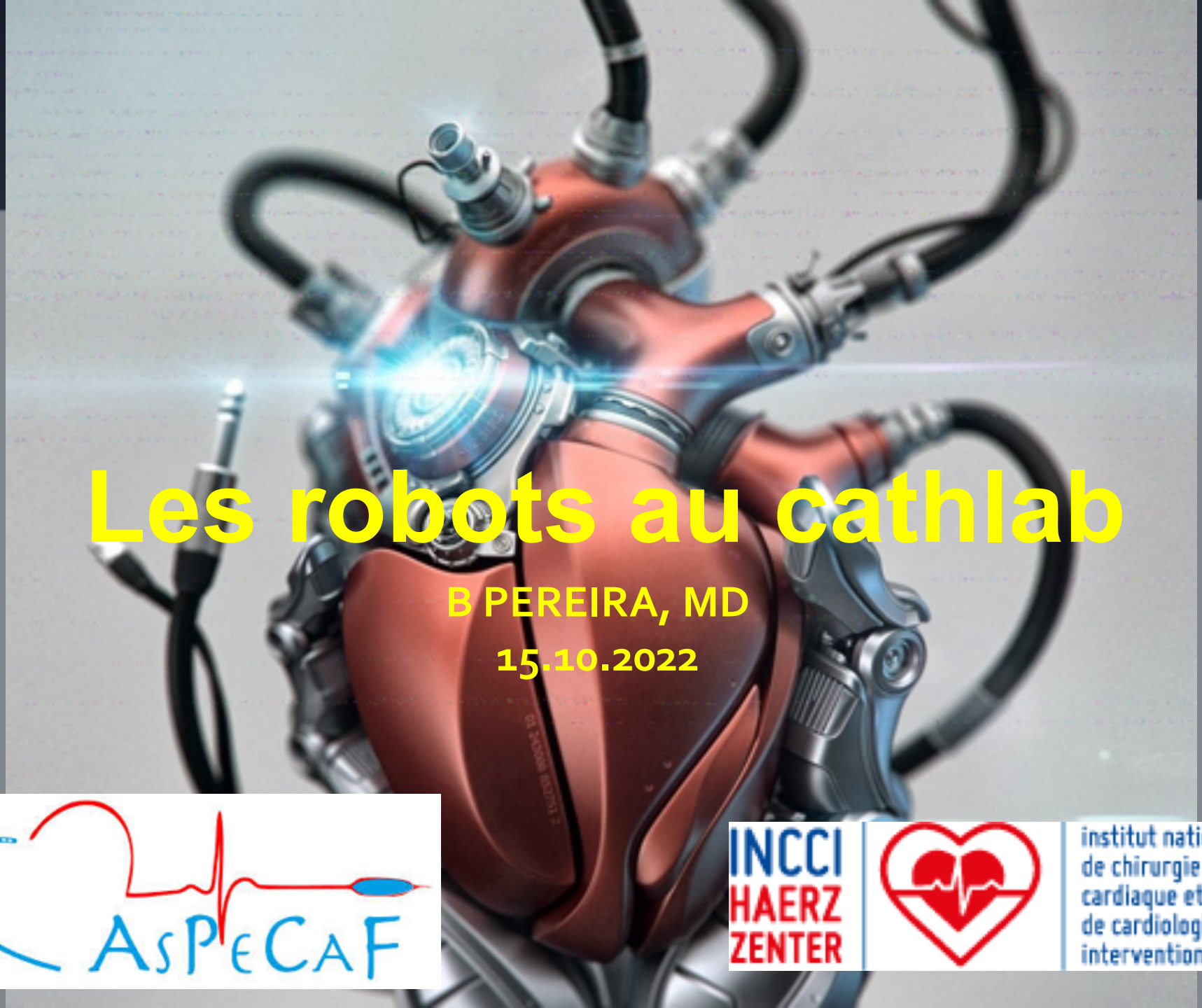


Les robots au cathlab

B PEREIRA, MD

15.10.2022

ASPECAF

INCCI HAERZ ZENTER

institut national de chirurgie cardiaque et de cardiologie interventionnelle

Conflits d'intérêts

- Aucun

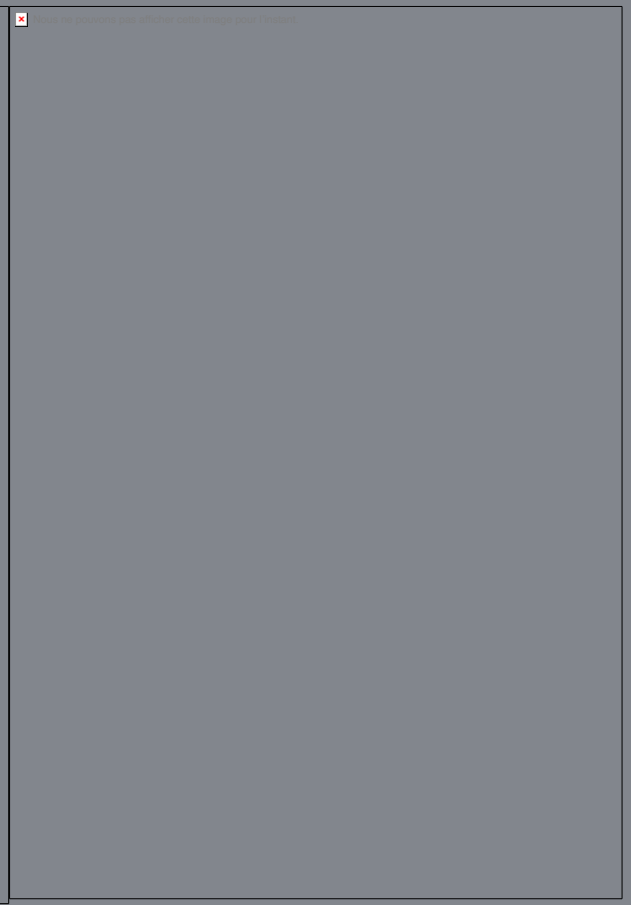
Sauf cardiologue interventionnel

Les robots au cathlab?

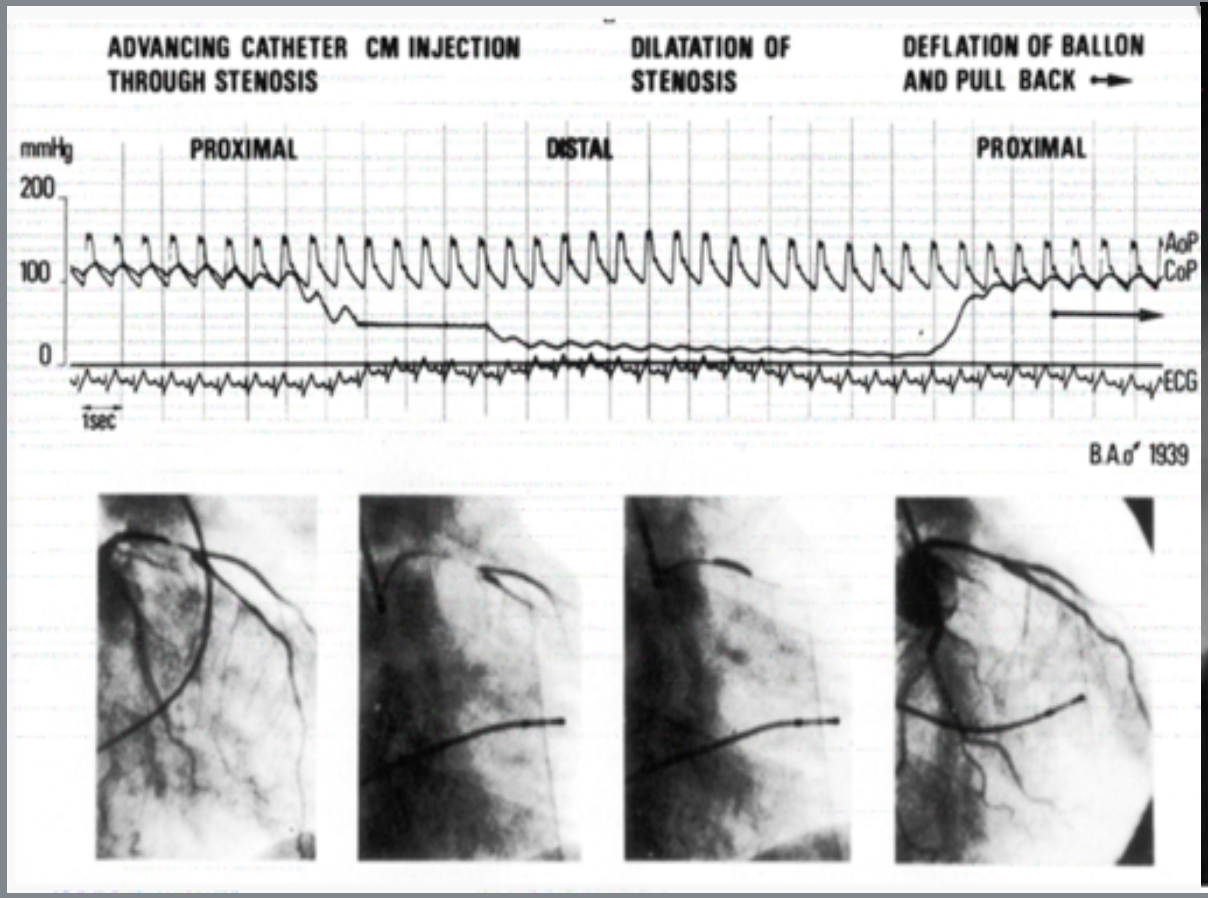
Pourquoi ?

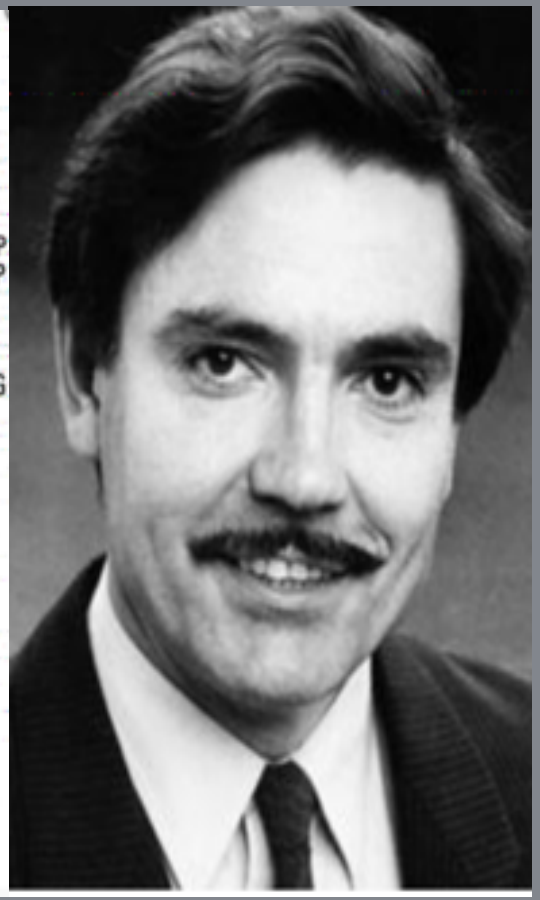
Werner Forsmann

1929

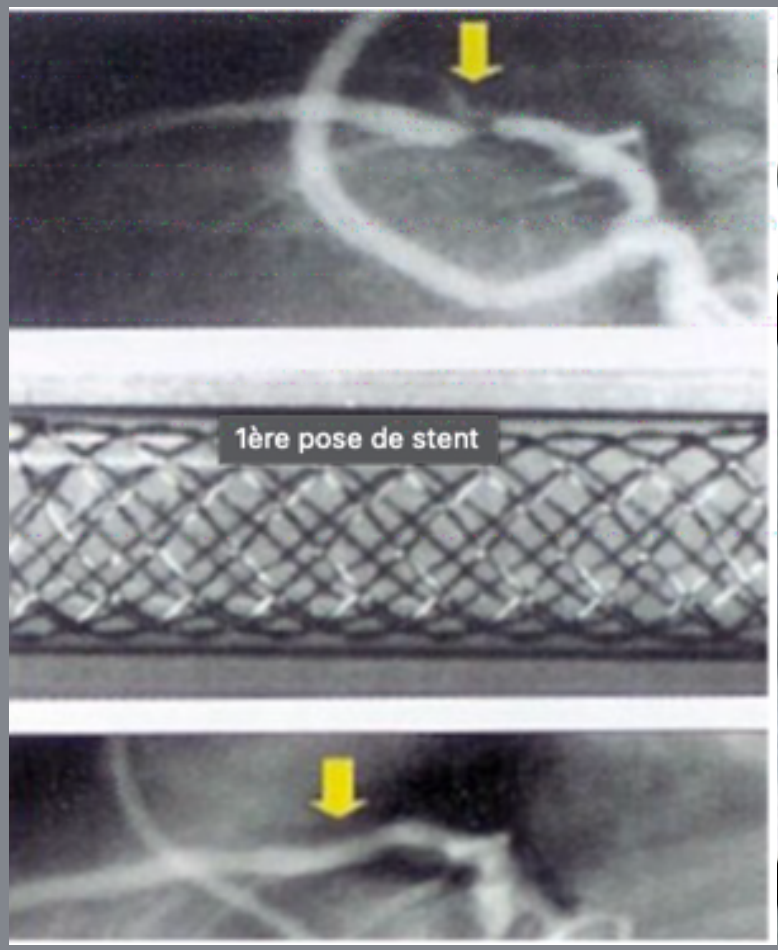


Andreas Gruentzig 1977



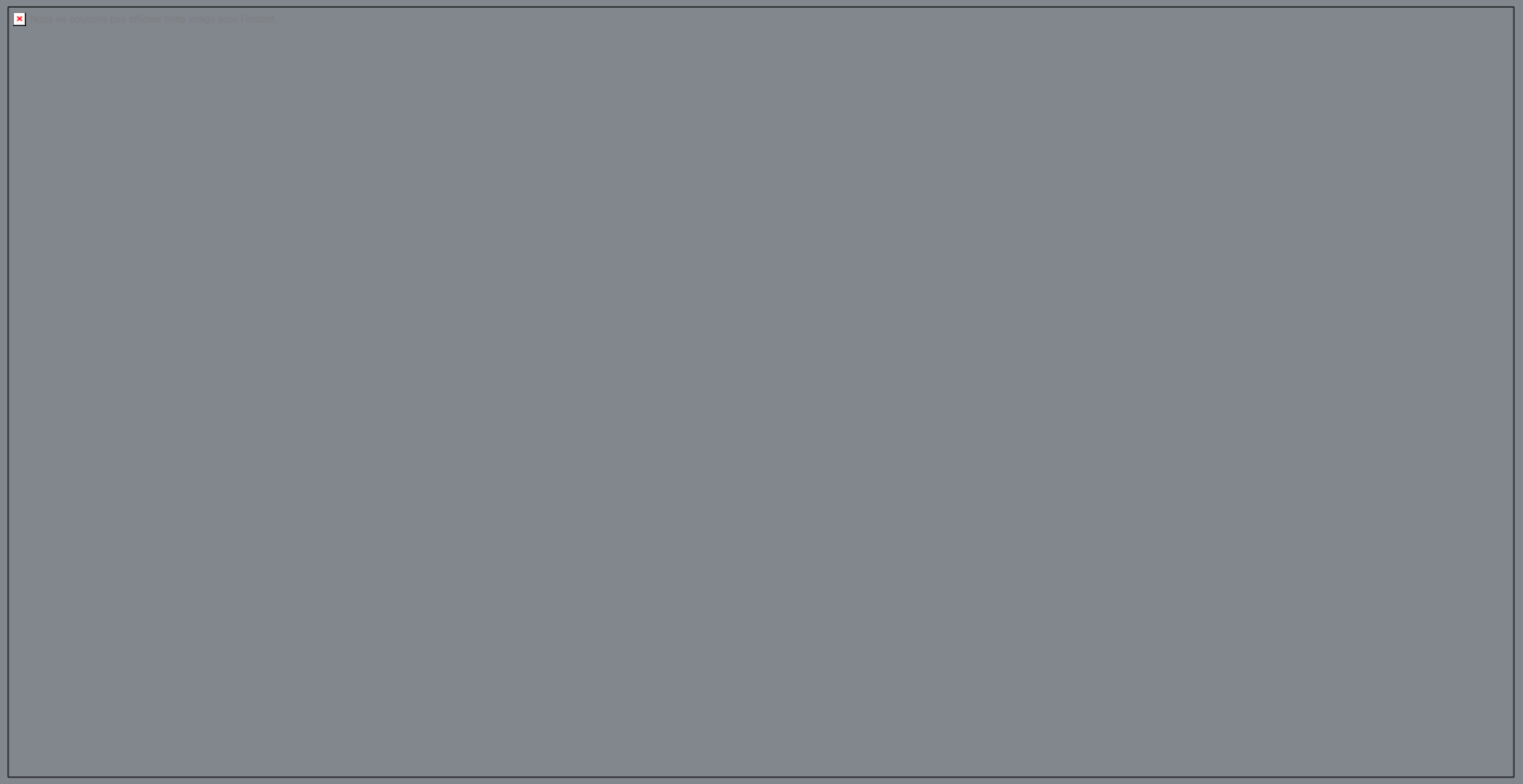


Jean-Jacques Puel
1986



Alain Cribier

2002



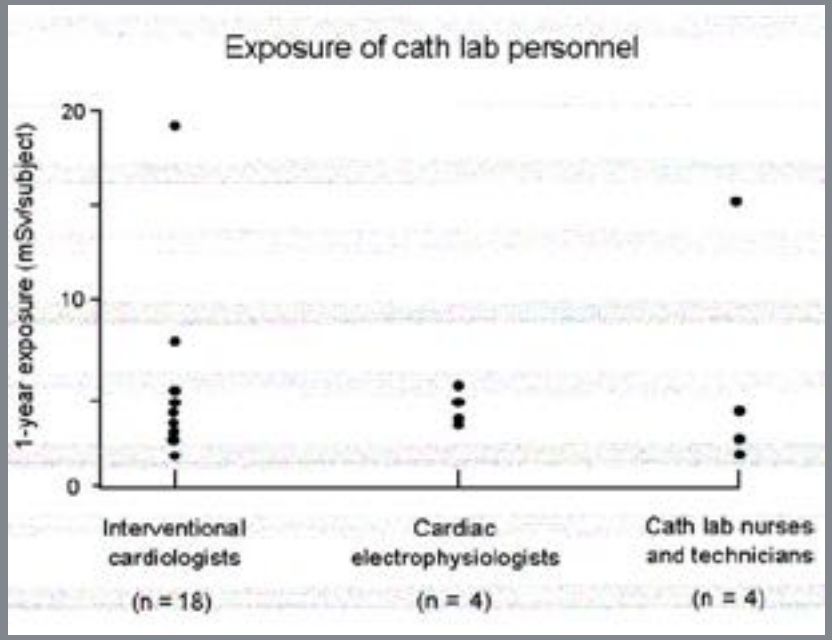
Evolution

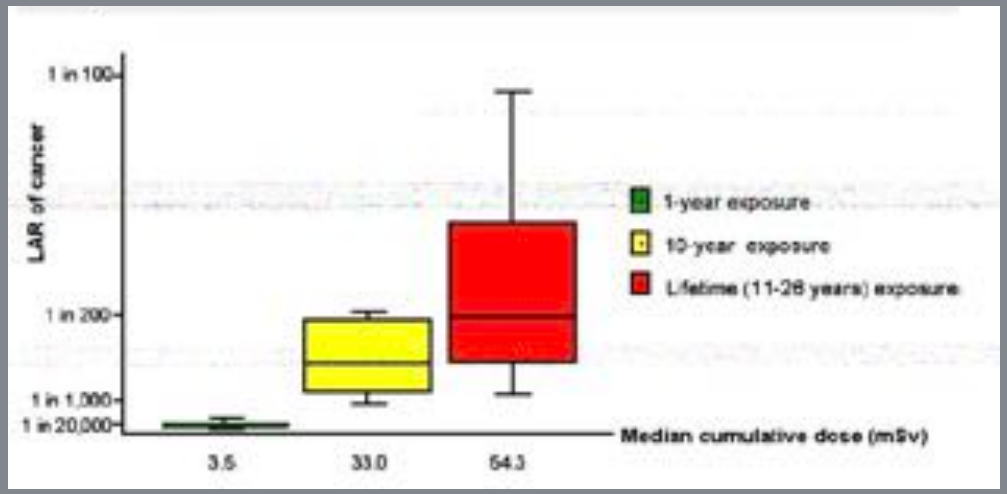
Rayons X

W. Roentgen

22.12.1895

Exposition





Venneri et al Am Heart J 2009;157:118-24

Radiation effects analysis in a group of interventional radiologists using biological and physical dosimetry methods

M. Ramos[a,*], A. Montoro[b], M. Almonacid[b], S. Ferrer[a], J.F. Barquinero[c], R. Tortosa[b], G. Verdú[a], P. Rodríguez[c], L.L. Barrios[d], J.I. Villaescusa[b]

[a] Department of Chemical and Nuclear Engineering, Polytechnic University of Valencia, Camino de Vera s/n, 46022 Valencia, Spain
[b] Radiation Protection Service, Hospital Universitario La Fe Valencia, Spain
[c] Biological Dosimetry Service, Unit of Anthropology, Department of Animal and Vegetable Biology and Ecology, Universitat Autonoma de Barcelona (UAB), Spain
[d] Department of Physiology and Cellular Biology, Unit of Cellular Biology (UAB), Spain

Average excess absolute risk (EAR) per sex for incidence cancer from the Life Span Study cohort included in the UNSCEAR 2006 and in [24].

	Cancer type	EAR (10^{-4} per PY Sv)	
		Male	Female
Solid cancer	Non-melanoma skin cancer [a]	0.38 [0.0, 1.1]	0.32 [0.0, 1.1]
Non-solid cancer	Leukemia	4.14 [3.06, 5.39]	2.41 [1.71, 3.23]
	Hodgkin's disease	0.04 [0.01, 0.3]	0.04 [0.01, 0.3]
	Non-Hodgkin's lymphoma	0.46 [0.04, 1.16]	0.0 [< 0 [b], 0.28]
	Multiple myeloma	0.26 [< 0 [b], 0.4]	0.08 [< 0 [b], 0.4]

Ramos et al. European Journal of Radiology 75 (2010) 259

Néoplasie cérébrale

Patient characteristics

	Country	Year Diagnosed	Age at Diagnosis (yrs)	Gender	Radiation Exposure (Latency Period) (yrs)	Tumor Type	Side Involved	Occupation	Prognosis	Age at Death (yrs)	Survival After Diagnosis	Reference
1	Toronto, Canada	1997	62	M	20	GBM	Left side	IC	Died in 1999	64	2 yrs	13,15
2	Toronto, Canada	1997	53	M	20	GBM	Left side	IC	Died in 1999	55	4 yrs	13,15
3	Haifa, Israel	1998	48	M	12	Meningioma	Left temporal	IC	Alive			15
4	Paris, France	2001	56	M	25	GBM	Left temporal	IC	Died in 2005	59	4 yrs	15
5	Paris, France	2005	49	M	22	GBM	Left temporo-occipital	IC	died in 2006	50	16 mo	15
6	Haifa, Israel	2009	62	M	32	GBM	Left frontal	IC	Died in 2010	63	11 mo	15
7	Sweden	NA		M	20	Acoustic neurinoma	NA	IR				14,15
8	Sweden	NA		M	28	Meningioma	NA	IR				14,15
9	Sweden	NA		M	31	Oligodendroma	NA	IR				14,15
10	London, UK	2009	62	M	27	Parotids	Left	IC				16
11	Zürich, Switzerland	2009	53	M	20	GBM	Left frontal	Pediatric EP	Died in 2010	54	14 mo	16
12	Virginia	2009	67	M	29	GBM	Left	EP	Alive			16
13	Dundee, Scotland	2007	59	M	29	Astrocytoma	Left	IC	Died in 2009	61	2 yrs	16
14	Kentucky	2008	54	M	22	GBM	Left	IC	Died in 2010	56	2 yrs	16
15	Illinois	2003	65	M	32	GBM	Midline	IC	Died in 2005	67	2 yrs	16
16	Gainesville, Florida	1990s	~40	M	~10	GBM	Left occipital lobe	IC		NA		16
17	West of Scotland	2008	52	Female	NA	GBM	Left frontal	Radiologist	Died in 2009	53	1 yr	16 + new data
18	West of Scotland	2011	NA	M	NA	GBM	Left temporal	IR	Alive			16 + new data
19	Leipzig, Germany	2005	55	M	20	GBM	Right	IC		56	1 yr	New
20	Homburg, Germany	2010	54	M	25	Astrocytoma (grade III)	Left	IC	Alive			New
21	Linköping, Sweden	2009	49	M	12	GBM	Left frontal lobe	IC	Died in 2011	49	2 yrs	New
22	Santa Monica, California	2006	52	M	21	GBM	Left	IC	Died in 2007	53	2 yrs	New
23	California	2008	71	M	22	Glioma	Left temporal	IC	Alive			New
24	Maryland	2012	57	M	26	Meningioma	Right	IR	Alive			New
25	Belgium	1990s	NA	M	NA	GBM	NA	IC	Died	NA		New
26	Belgium	1990s	NA	M	NA	GBM	NA	IC	Died	NA		New
27	Ireland	2011	55	M	31	Neck lymphoma	Left	IC	Alive			New
28	Israel	2012	62	M	32	Parotids	Right	IC	Alive			New
29	Germany	2003	49	M	19	Meningioma	Left	IC	Alive			New
30	Middle East	2009	62	M	30	Meningioma	Left	IC	Alive			New
31	Middle East	2009	52	M	19	Tonsillar tumor	Left	IC	Alive			New

EP = electrophysiologist; F = female; GBM = glioblastoma multiforme; IC = invasive cardiologist; IR = invasive radiologist; M = male; NA = not available.

Roguin Am J Cardiol 2013;111:1368

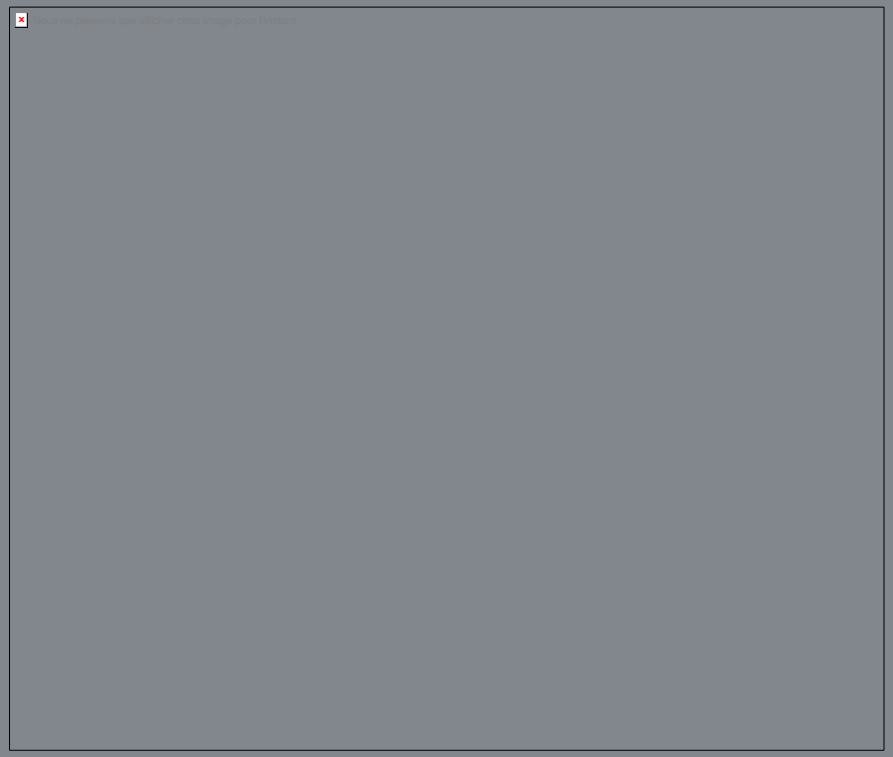
Nous ne pouvons pas afficher cette image pour l'instant.

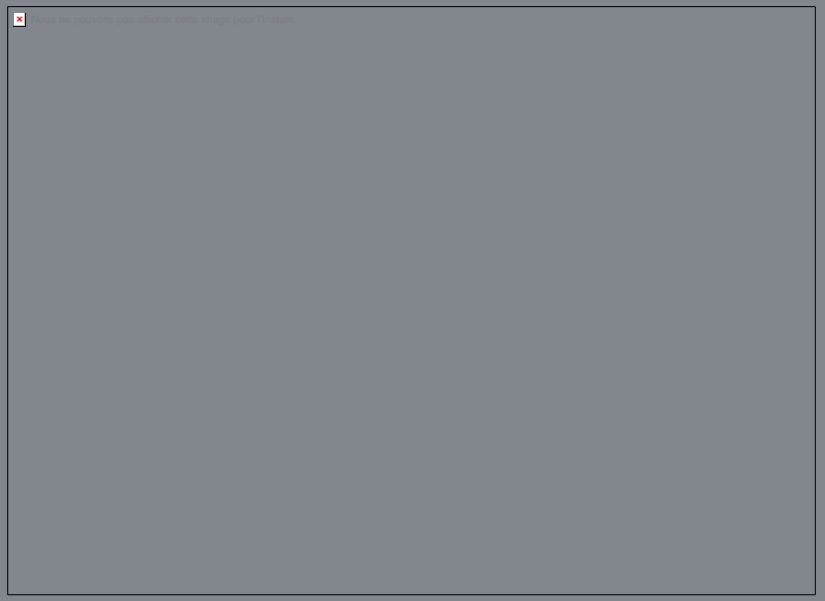
Table 2 Lifetime attributable cancer risks with respect to job title at mean cumulative occupational radiation dose among workers at interventional radiology departments

Organ sites	Male radiologists		Male radiologic technologists		Female nurses	
	LAR	LFR (%)	LAR	LFR (%)	LAR	LFR (%)
All	338.0 (90.3–796.1)	0.63 (0.17–1.47)	121.0 (33.5–288.7)	0.22 (0.06–0.53)	156.0 (41.1–390.6)	0.39 (0.10–0.97)

Lee et al. Inter Arch of Occupational and Environmental Health (2021) 94:139

Effets chromosomiques



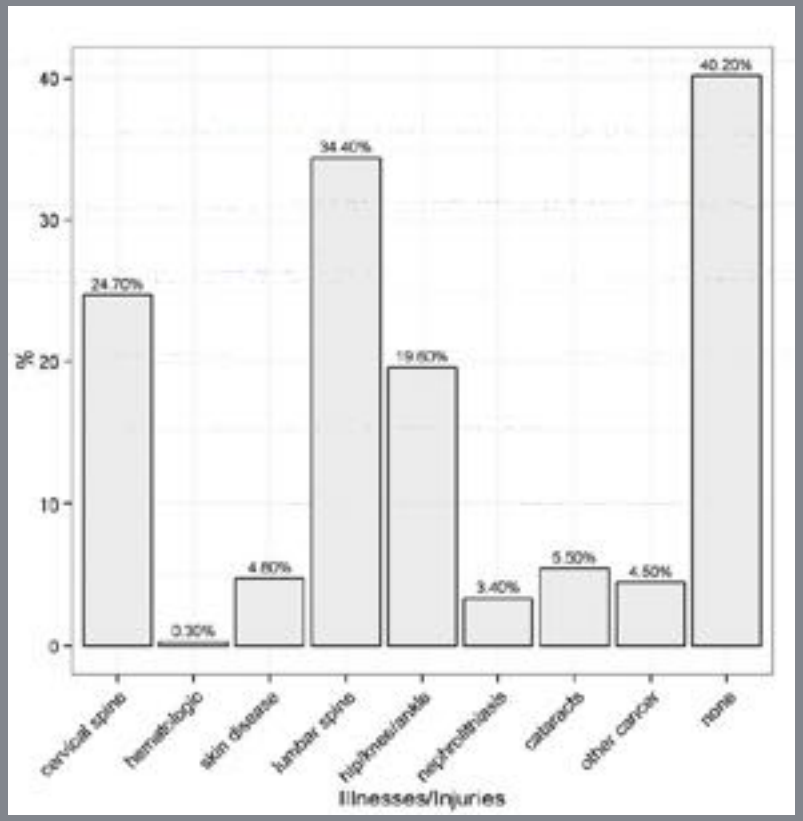


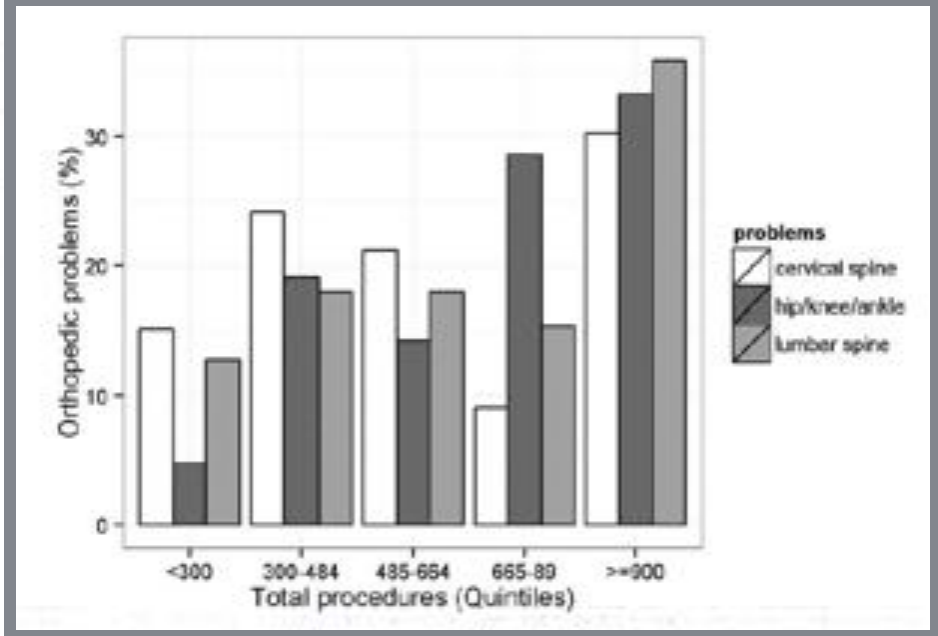
Lee et al. European Radiology (2021) 31:8256

Daniel Wagner

R.I.P.

Lésions orthopédiques





Klein et al. 2015 Cath and Cardiovasc Interv 86:913

PCI robo-assistée: Pro/Contra

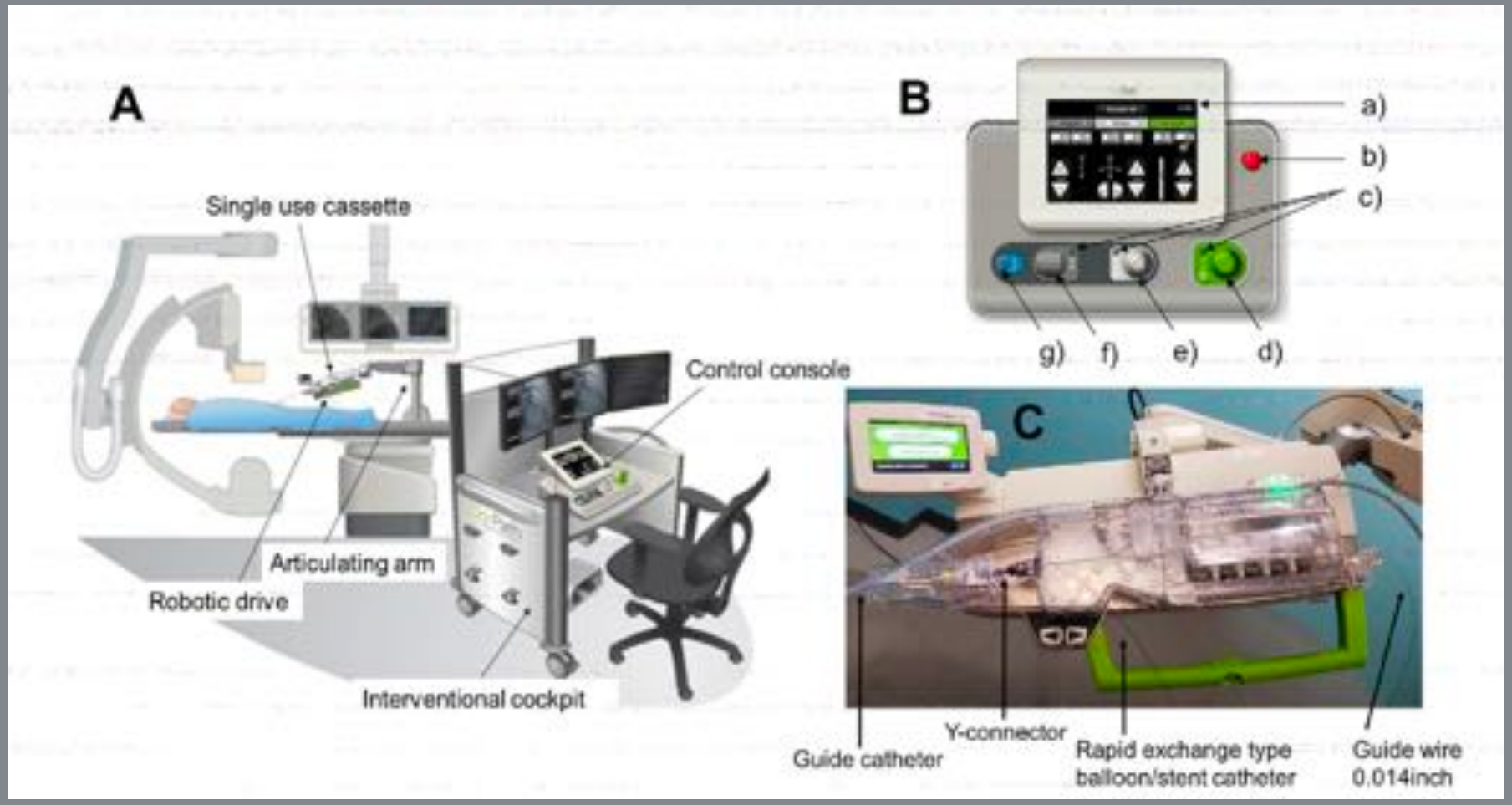
Avantages

- Reduction de l'incidence du "longitudinal geographical miss"
- Reduction Rx pour opérateur et patient
- Reduction lésions orthopédiques
- Opérateur réalise des procédures à distance

Limitations

- Incompatibilité avec différents devices (ROTA, over-the-wire, OCT & IVUS)
- Impossibilité de manipuler multiples stents et catheters
- Temps d'installation allongé pour PCI primaires
- Délai lors de complications

Premier Robot :
The CorPath GRX system



PRECISE

Table 2 Quantitative Angiographic Analysis

Variable	Pre-Procedure	Post-Procedure
LAD	55 (33.5%)	
Main LAD	53 (32.3%)	
Diagonal	2 (1.2%)	
LCX	47 (28.7%)	
Main LCX	35 (21.3%)	
Ramus intermedius	8 (4.9%)	
Obtuse marginal	4 (2.4%)	
RCA	62 (37.8%)	
Main RCA	60 (36.6%)	
Posterior descending	2 (1.2%)	
ACC/AHA class		
A	47 (28.7%)	
B1	65 (39.6%)	
B2	31 (18.9%)	
C	21 (12.8%)	
Lesion length (mm)	12.2 ± 4.8	
Reference vessel diameter (mm)	2.66 ± 0.45	2.73 ± 0.46
MLD (mm)	0.96 ± 0.33	2.59 ± 0.43
Diameter stenosis (%)	64.10 ± 10.9	4.90 ± 7.85

Table 3 In-Hospital and 30-Day Follow-Up Outcomes (n = 164)

In-hospital	
Death	0 (0.0)
MI (all)	4 (2.4)
Q-wave	0 (0.0)
Non-Q-wave	4 (2.4)
TLR	0 (0.0)
MACEs	4 (2.4)
Out-of-hospital to 30 days	
Death	0 (0.0)
MI (all)	0 (0.0)
Q-wave	0 (0.0)
Non-Q-wave	0 (0.0)
TLR	0 (0.0)
MACEs	0 (0.0)
All events to 30-day follow-up	
Death	0 (0.0)
MI (all)	4 (2.4)
Q-wave	0 (0.0)
Non-Q-wave	4 (2.4)
TLR	0 (0.0)
MACEs	4 (2.4)
Stent thrombosis, 0–30 days	0 (0.0)

Weisz et al JACC 2013;61:1596–600

CORA-PCI trial

TABLE 3 Procedural Characteristics and Clinical Outcomes of Both the Study (Robotic) and Control (Manual) Groups in the Entire Study Cohort

	Robotic Group (n = 108)	Manual Group (n = 226)	p Value
Access site			
Femoral	88%	87.6%	0.93
Radial	12%	12.4%	0.93
Stents deployed	1.59 ± 0.79	1.54 ± 0.75	0.73
Procedure time (min:s)	44:30 ± 26:04	36:34 ± 23:03	0.002
Dose-area product (cGy · cm²)	12,518 ± 15,970	14,048 ± 18,437	0.045
MACE*	0.9%	0.9%	1.00
CK-MB >3 times ULN	5.6%	7.5%	0.51

FIGURE 4 Procedure Time, Robotic Versus Manual PCI

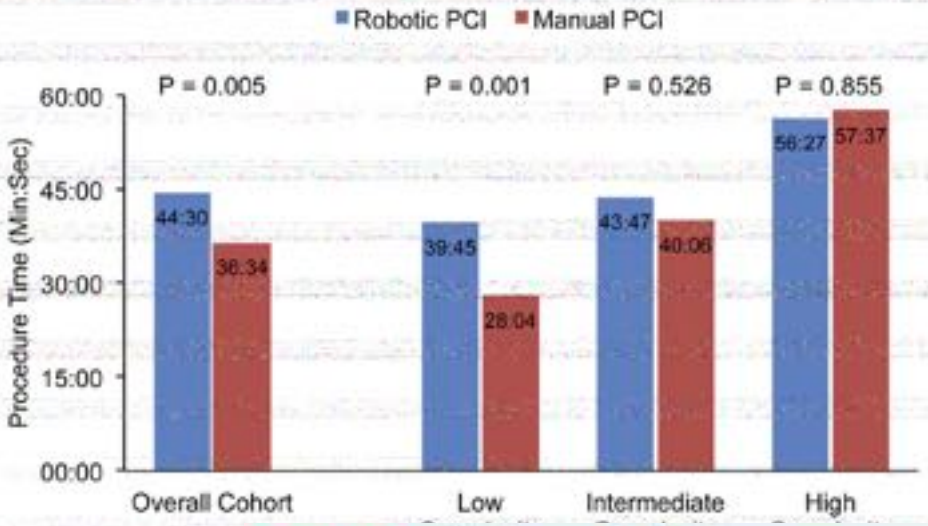
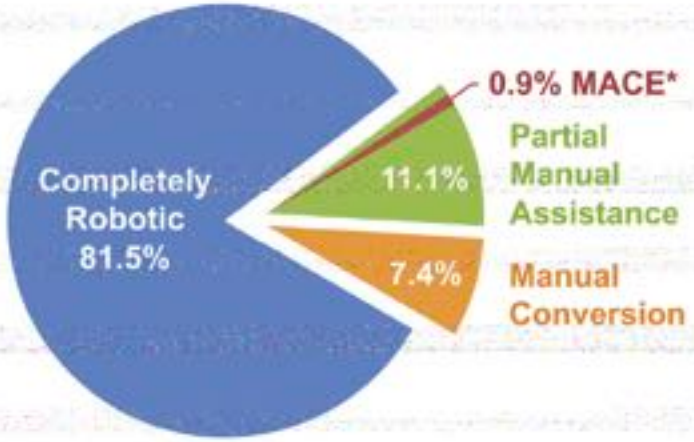


FIGURE 3 Technical Success of Robotic Percutaneous Coronary Intervention



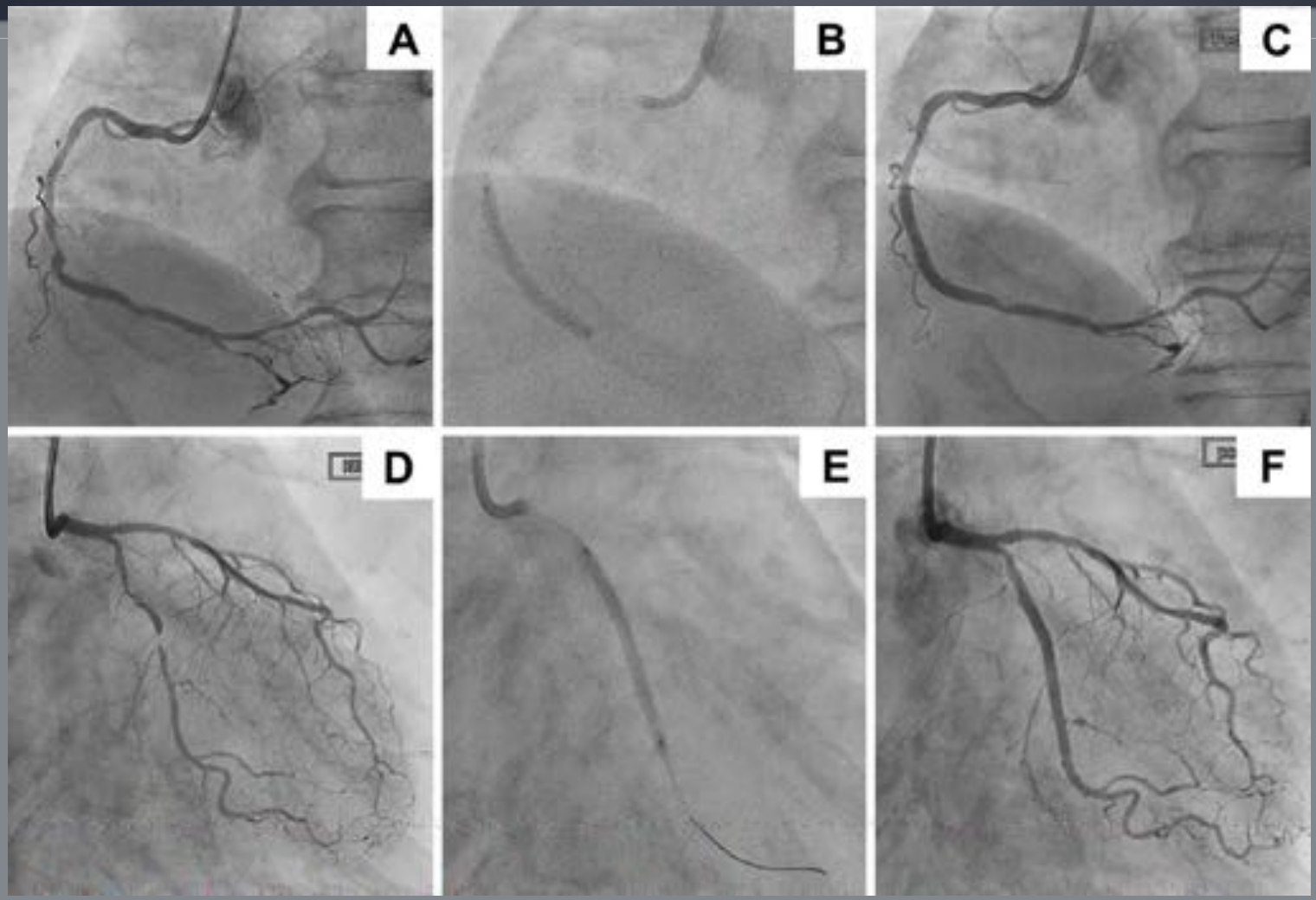
Mahmud et al JACC Interv 2017;10:1320

2ème génération: manipulation catheter

- Prospectif, multicentrique
- 40 pts
- Exclusion: STEMI, CTO, ROTA
- Lésion B2/C: 77,8%
- Succès technique: 90%
- Succès clinique: 97,5%
- MACCE: 0%

Smitson et al. J Invasive Cardiol 2018;30(4):152

Japan experience



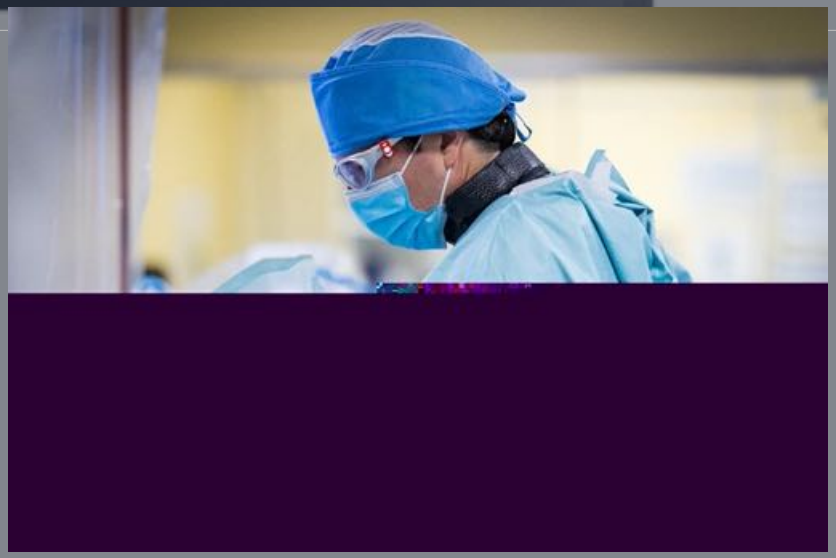
Kagiyama Intern Med 2019 58: 3415

Robocath


R-one
ROBOTIC ASSISTED PCI
by Robocath
Monitors (duplication)
MOBILE RADIOPROTECTION CONTROL STATION
Command unit + mobile radioprotection screen
TELEMANIPULATED ROBOTIC UNIT
Robot + articulated supported arm
Catheter joystick
Guidewire joystick
Guidewire path
Stand-by path
Catheter path
Contrast command
Table and C-arm command (duplication)
ROBOT
Guidewire clamp button
Release arm braking
COMMAND UNIT

1ère expérience 04.2018

FIM Luxembourg
06.2021



R-evolution

Study conducted in Europe

- prospective, multicenter, single arm
- 62 patients
- 6 Centers
- Indication: de novo, up to 2 lesions in a single procedure (1 lesion per vessel)
- Exclusion criteria: length > 38mm, diameter > 4.00mm, severe calcification and tortuosity, bifurcations, ostial lesions, restenosis, LM, SVGs…
- Follow-up : 1 month
- Primary endpoints:
  - Clinical Success: absence of intra-procedural complications defined as coronary dissection ≥ NHLBI type D, perforation, decrease of TIMI flow (≤2), acute occlusion, visible thrombus formation, significant air embolus during the procedure, traumatic aortic or left main dissection by guiding catheter.
  - Procedural Technical Success: successful advancement and retraction of all PCI devices (guidewires, balloon catheters and stents) and the successful treatment of all the target lesions using the R-One™ System and without conversion to manual operation.
- Start date: Q4 2019
- Ending date : Q3 2021

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Caen University Hospital
Caen

Dr. J. FAJADET
Clinique Pasteur
Toulouse

Baseline clinical characteristics

Variables	Overall population (N=62)
Age, years	65.4 ± 10.1
Male, N (%)	50 (80.6)
BMI, Kg/m²	27.2 ± 4.7
Risk factors, N (%)	
Current smoker	14 (22.6)
Diabetes	17 (27.4)
Hypercholesterolemia	35 (56.4)
Hypertension	33 (53.2)
Family history of CAD	19 (30.7)
Medical history, N (%)	
Previous MI	9 (14.5)
Previous PCI	15 (24.2)
Previous CABG	2 (3.2)
History of Cerebrovascular disease	5 (8.1)
PAD	8 (12.9)
Chronic renal failure	4 (6.5)
Atrial fibrillation	5 (8.1)
Clinical presentation, N (%)	
Silent ischemia	23 (37.1)
Stable angina	26 (41.9)
Unstable angina	6 (9.7)
NSTEMI	7 (11.3)

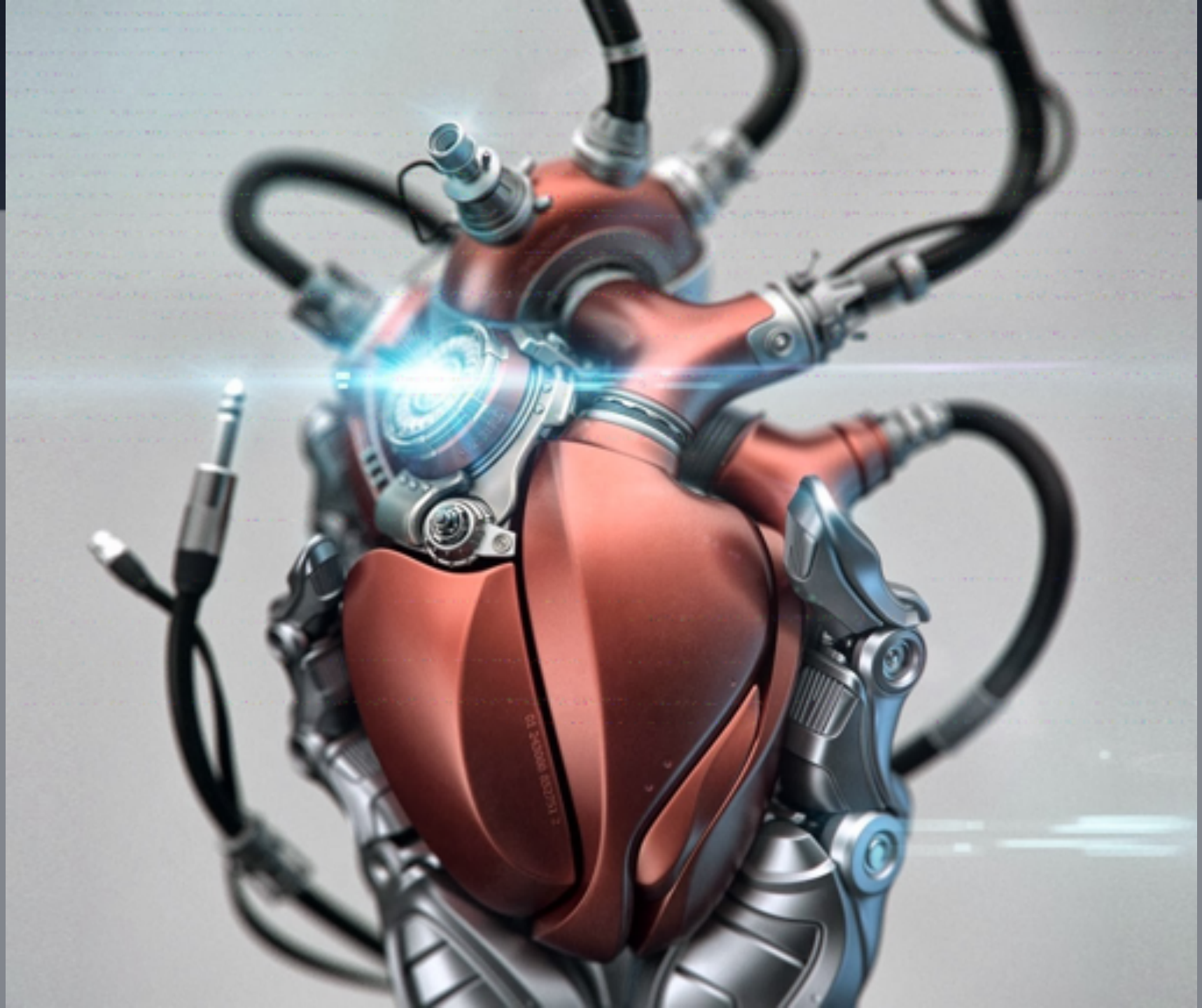
Procédures

Variables	Overall population (62 patients, 64 lesions)
Approach, N (%)	
Right radial artery	**50 (80.6)**
Left radial artery	**10 (16.1)**
Right femoral artery	2 (3.2)
Left femoral artery	0 (0)
Lesion location, N (%)	
LAD	**22 (34.4)**
LCX	**21 (32.8)**
RCA	**17 (26.5)**
Other (Ramus)	**4 (6.3)**
Lesion class (ACC/AHA), N (%)	
A	11 (17.2)
B1	37 (57.8)
B2	**13 (20.3)**
C	**3 (4.7)**
PCI	
Sheath size (6F), N (%)	62 (100)
Pre-dilatation, N (%)	**38 (59.4)**
Stent per lesion	1.05 ± 0.28
DES, N (%)	67 (100)
Stent diameter, mm	3.0 ± 0.4
Stent length, mm	19.5 ± 6.5
Post-dilatation, N (%)	**24 (37.5)**

Radial access = 96,8%

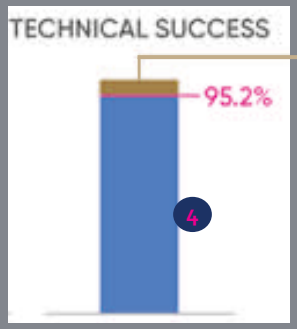
Homogeneous distribution

25% of complex lesions



Robotic PCI with R-One™: safety & efficacy demonstration

1

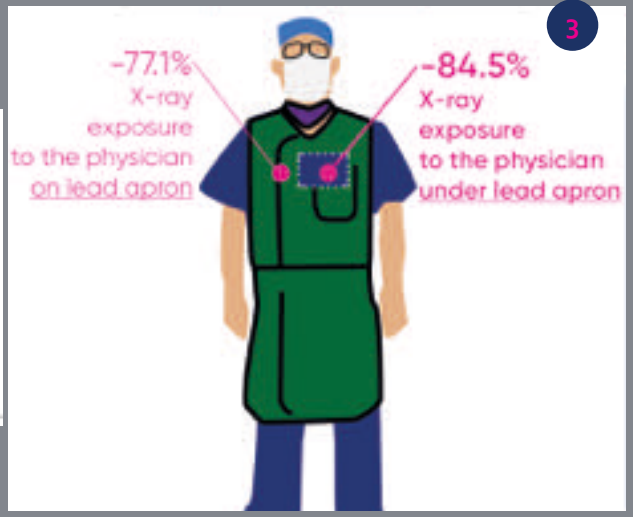


- Inability to cross the lesion with the balloon due to a lack of support (1/3)
- Software error due to wrong adjustment of the guidewire into the pads of the robot (1/3)
- A non-occlusive coronary dissection (NHLBI type B) unrelated to the robot (1/3)

62 patients included

2

3



KEY FINDINGS

1. >95% technical success
2. 100% clinical success: no major procedural or 30-day complications reported
3. 84.5% average reduction in physician radiation exposure
4. 100% technical success achieved in experienced centers*

*For each experinced center, more than 5 robotic PCI were performed before patient enrollment in the study and each investigator from these centers were involved in preclinical studies

L’avenir

?

Conclusion

Pourquoi pas ?

La seule question stupide est celle qu'on n'a pas osé poser.

Proverbe chinois