**SOCIETÀ MEDICA
DI SANTA MARIA NUOVA**

XI EDIZIONE

**Giornate Mediche di
Santa Maria Nuova 2019**

Elettrofisiologia “senza Raggi X e senza fili”

L'Ospedale dei Fiorentini

Dott.ssa Marzia Giaccardi
Laboratorio di Elettrofisiologia
UOS di Cardiologia ed Elettrofisiologia
Santa Maria Nuova - Firenze

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Tema di questa edizione: Progettualità ed innovazioni a Santa Maria Nuova e nell'Azienda USL Toscana Centro: tra scienza, aspetti normativi e sostenibilità, con l'obiettivo di focalizzare l'attenzione sulle molteplici iniziative che l'Azienda sanitaria ed i suoi Dipartimenti ospedalieri stanno portando avanti in settori molto diversi.

Che cos'è la sostenibilità?

- «Nelle scienze ambientali ed economiche, la «sostenibilità» è la condizione di uno sviluppo in grado di assicurare il **soddisfacimento dei bisogni della generazione presente senza compromettere la possibilità delle generazioni future di realizzare i propri**»¹
- La sostenibilità è, quindi, un concetto relativo, che implica una decisione politica sull' **allocazione delle risorse rispetto a possibili usi alternativi**

Responsabilità

Ogni modello di sviluppo è frutto di una **scelta fra diverse opzioni di cui siamo responsabili nei confronti della nostra e delle future generazioni**

Limiti

Le risorse naturali non sono illimitate. Esistono equilibri che possono essere irrimediabilmente alterati da modelli inadeguati di produzione e di consumo e da una scorretta politica ambientale

Sviluppo
sostenibile

Complessità

Ogni scelta deve essere operata tenendo conto **dei suoi effetti in una complessità di ambiti** tra loro interrelati.

Sostenibilità economica = sfida per i sistemi sanitari

“La Santé par Le Radium ”

The **28 December 1895** by the official announcement of Roentgen's discovery of x-rays to the president of the Physical Medical Society of Wurzburg;

The **12 April 1898** Marie Sklodowska Curie announced to the Académie des Sciences in Paris the discovery of Polonium - Radium.

Two dates that mark a turning point in the history of medicine.

Marie e Pierre Curie. Primo Nobel, nel 1903 per la Fisica e 1911 per la Chimica.

We Are Giving Ourselves Cancer

By RITA F. REDBERG and REBECCA SMITH-BINDMAN JAN. 30, 2014

Neither doctors nor patients want to return to the days before CT scans. But we need to find ways to use them without killing people in the process.

**EXPOSED WORKERS : 22.8 millions (plus military personnel);
of them, 7.8 millions medical workers (UNSCEAR 2008)**

The dark side of the moon

MERCOLEDÌ 26 NOVEMBRE 2003

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INTERVISTA CON IL CHIMICO PREMIO NOBEL HOFFMANN

Il vero problema è che non vogliamo vedere i lati oscuri di ciò che rende la nostra vita migliore, e li rimuoviamo.

E non solo nel campo chimico!

Roald Hoffmann, premio Nobel per la Chimica

The appropriate and justified use of medical radiation in cardiovascular imaging: a position document of the ESC Associations of Cardiovascular Imaging, Percutaneous Cardiovascular Interventions and Electrophysiology

Take-home message

All other considerations being equal, it is not recommended to perform tests involving ionizing radiation when the desired information can be obtained with a non-ionizing test with comparable accuracy. If you perform a test that utilizes ionizing radiation, choose the one with the lowest dose and be aware of the many factors modulating dose. The actual delivered dose should always be recorded and included in patients' records. Because of the numerous sources of variability, there is no clear threshold between acceptable and unacceptable exposure for any given examination, but the dose that is not even considered is certainly unacceptable.

X-rays and γ -rays used in radiology and nuclear medicine are proven (class 1) carcinogens, and cardiologists should make every effort to give 'the right imaging exam, with the right dose, to the right patient'.⁵⁰ The priority given to radioprotection in every cardiology department is an effective strategy for primary prevention of cancer, a strong indicator of the quality of the cardiology division, and the most effective shielding to enhance the safety of patients, doctors, and staff. A smart cardiologist cannot be afraid of the essential and often life-saving use of medical radiation, but must be very afraid of radiation unawareness.

Exposure to Low-Dose Ionizing Radiation From Cardiac Procedures and Malignancy Risk in Adults With Congenital Heart Disease

Cumulative risk of cancer for patients with CHD over the course of adulthood up to 64 years, adjusted for competing risk of death.

1 of 7 men (14.4%; 95% CI, 12.7–16.0)

1 of 6 women (16.1%; 95% CI, 14.5–17.8)

developed cancer between 18 and 64 years of age

The incidence rate of cancer progressively increased with advancing age, and 310 (51.5%, tot 602) of cancer cases occurred in the 55 to 64 years age group.

Choen et al. Circulation 2018;137:1334–1345

Adjusted Kaplan-Meier* curve for cancer-free survival probability for patients with high exposure from LDIR-related cardiac procedures (at least 6 procedures, dashed line) in comparison with low exposure (0 or 1 procedure, solid line).

The cumulative risk of cancer at 15 years was 8.5% (95% CI, 7.8–9.1%) in patients with high LDIR exposure versus 3.3% (95% CI, 3.0–3.6%) in patients with low LDIR exposure ($p < 0.0001$)

HR of **2.4** (95% CI, 2.1–2.7) for cancer risk in the high LDIR exposure group in comparison with the low LDIR exposure group, after adjustment for age, sex, year of birth, CHD severity, comorbidities, surgical history, and competing risk of death.

L'esposizione radiologica nelle procedure EP

ESPOSIZIONE PER DIAGNOSTICA MEDICA A LIVELLO MONDIALE

E' stato stimato che questo tipo di esposizione è maggiore nei paesi occidentali. (2008, UNSCEAR)

Brain tumor in the cath lab

"The left side is the side usually exposed to more radiation. Of legal importance, recently, the brain tumor of one physician was recognized by the legal authorities in his country as a professional disease related to his work and exposure to radiation in the catheterization laboratory"³

1. Kim, KP, et al. Occupational radiation doses to operators performing cardiac catheterization procedures. Health Phys. 2008, Vol. 94, 3, pp. 211-227
2. Vañó, E, et al. Radiation exposure to medical staff in interventional and cardiac radiology. Br J Radiol. 1998, Vol. 71, pp. 954-960
3. Roguin A. Radiation in cardiology: can't live without it! Eur Heart J 2014; 35: 599-600

L'esposizione radiologica nelle procedure EP

Sensibilità dei tessuti alle radiazioni ionizzanti

molto sensibili

- cellule emopoietiche
- tessuto linfatico
- spermatogoni
- follicoli ovarici

sensibili

- mucosa gastrointestinale
- cellule endoteliali
- follicoli piliferi
- mammella
- pancreas
- vescica
- cuore e polmoni

relativamente resistenti

- osso e cartilagine
- muscolo scheletrico
- tessuto nervoso

LOCALIZZAZIONE DEI PIÙ FREQUENTI TUMORI DA RADIAZIONI

Occupational radiation exposure in the electrophysiology laboratory with a focus on personnel with reproductive potential and during pregnancy: A European Heart Rhythm Association (EHRA) consensus document endorsed by the Heart Rhythm Society (HRS)

Occupational exposure to potentially hazardous factors including **radiation can impact both male and female reproductive health.** And even more the radiation exposure can determine:

Transient sperm count deterioration was observed between 105 and 330 days after exposure. Short-term reduction of sperm counts can be expected after absorbing of radiation dose in the range of 0.11–0.15 Gy, while 2–3 Gy may result in **long-lasting or permanent sterility.**

Radiation might induce **alterations in the hypothalamic–pituitary axis function influencing fertility** and outcome of pregnancy. However, in human no data are yet available on the presence and importance of these effects.

The fetus is most sensitive to radiation effects between 8 and 15 weeks of pregnancy during organogenesis, with the same risk for potential carcinogenic effects of radiation as in the children.

...in addition to cancer.....

Chronic low-dose-rate ionising radiation affects the hippocampal phosphoproteome in the ApoE^{-/-} Alzheimer's mouse model

This study shows that several molecular targets induced by chronic low-dose-rate radiation overlap with those of Alzheimer's pathology. It may suggest that ionising radiation functions as a contributing risk factor to this neurodegenerative disease.

Kempf et al. Oncotarget 2016;7:71817- 71832

RESEARCH LETTER

EDITORIAL

Low-Dose Exposure to Ionizing Radiation Deregulates the Brain-Specific MicroRNA-134 in Interventional Cardiologists

Borghini et al. Circulation 2017;136:2516-2518

Health Risks of Ionizing Radiation

Dr Roentgen Today

Because dysregulated miRNA is seen in **certain forms of epilepsy, Alzheimer's disease, and brain cancers**, this supports concerns for potential brain malignancies or **long-lasting cognitive impairment**.

Chambers. Circulation 2017;136:2417-2419.

...in addition to cancer.....

A 6 × higher rate of self-described anxiety/depression in the exposed staff.

Andreassi et al. *Circ Cardiovasc Interv.* 2016;9:e003273

Journal of the International Neuropsychological Society

Memory abnormalities 10-fold more prevalent

Marazziti et al. *JINS* 2015;21: 670-676

Olfactory non-cancer effects of exposure to ionizing radiation in staff working in the cardiac catheterization laboratory[☆]

Olfactory abnormalities 3-fold more prevalent in exposed group

Tonacci et al. 2014 2014;3:461-463

The appropriate and justified use of medical radiation in cardiovascular imaging: a position document of the ESC Associations of Cardiovascular Imaging, Percutaneous Cardiovascular Interventions and Electrophysiology

Standard average reference doses of common cardiological examination

	Diagnostic procedures	Effective dose (mSv)	Equivalent CXRs
Adult	Conventional radiography CXR (PA)	0.02	1
Adult	Cardiac electrophysiology		
	Diagnostic EP studies	3.2 (1.3–23.9)	160
	Ablation procedure:	15.2 (1.6–59.6)	760
	AF	16.6 (6.6–59.2)	830
	AT-AVNRT-AVRT	4.4 (1.6–25)	220
	VT	12.5 (3 to ≥ 45)	625
	Regular PM or ICD implant	4 (1.4–17)	200
	CRT implant	22 (2.2–95)	1100
	CT		
	64-slice coronary CTA	15 (3–32)	750 (150–1600)
	Calcium score	3 (1–12)	150
	Nuclear cardiology		

Registry Procedural Data for Both Eras

	Early Era	Late Era
N _{Total}	4,193	3,407
No. of successful ablations (%)	3,790 (90.4%)	3,245 (95.2%)
Fluoroscopy time (min)	50.9 ± 39.9	40.1 ± 35.1
Complications	178 (4.2%)	100 (3.0%)
Age (years)	12.4 ± 4.7	12.2 ± 4.6

Values are given as number (%) or mean ± SD.

Exclusion of Fluoroscopy During Ablation Treatment of Right Accessory Pathway in Children

FABRIZIO DRAGO, M.D., MASSIMO STEFANO SILVETTI, M.D.,
ALFREDO DI PINO, M.D., GIORGIA GRUTTER, M.D., MAURIZIO BEVILACQUA, M.D.,
and SHOSHANA LEIBOVICH, M.D.

From the Pediatric Cardiology Department, Bambino Gesù' Hospital, Rome, Italy

21 consecutive WPW (due to a right AP) pediatric patients were submitted to radiofrequency ablation guided by CARTO system

Reduction of fluoroscopy time during the study. Considerable reduction is seen after procedure 8, with definitive elimination of fluoroscopy after procedure 12.

EFFICACIA TERAPEUTICA

“Near-zero” fluoroscopic exposure in supraventricular arrhythmia ablation using the EnSite NavX™ mapping system: personal experience and review of the literature

EnSite NavX™ system is feasible, safe, and effective in a population of relatively young adults. First report of non-fluoroscopic use for both left- and right-sided ablation in a non-pediatric population.
50 pts 38/50 ORX

Casella et al. J Interv Card Electrophysiol 2011;31:109-18.

Near-zero x-ray in arrhythmia ablation using a 3-dimensional electroanatomic mapping system: A multicenter experience

Near-zero-RX approach vs fluoro provides similar outcomes and may significantly reduce or eliminate ionizing radiation exposure in RFCA ... without altering the duration or compromising the safety and effectiveness of the procedure. 442 pts (145 RX; 297 ORX).

Giaccardi et al. Heart Rhythm 2016, 13:150-156

Long-term outcomes after “Zero X-ray” arrhythmia ablation

Tabella 2 Successo e tassi complicanze

Tipi di aritmie [n, %]	Successo in acuto [n, %]	Successo in cronico [n, %]	Complicazioni Maggiori [n, %]	Complicazioni Minori [n, %]
BEV [1, 0.4]	[1, 100.00]	[1, 100.00]	[0, 0.0]	[0, 0.0]
FA [3, 1.1]	[3, 100.0]	[3, 100.0]	[0, 0.0]	[0, 0.0]
FIA tipico [92, 33.8]	[92, 100.00]	[84, 91.3]	[0, 0.0]	[0, 0.0]
FIA atipico [2, 0.7]	[2, 100.00]	[2, 100.0]	[0, 0.0]	[0, 0.0]
Modulazione NAV [30, 11.0]	[30, 100.00]	[28, 93.3]	[0, 0.0]	[0, 0.0]
AVNRT [83, 30.5]	[83, 100.00]	[78, 94.0]	[1, 0.4]*	[1, 0.4]**
Tachicardia Atriale [25, 9.2]	[25, 100.00]	[23, 92.0]	[0, 0.0]	[0, 0.0]
Tachicardia Ventricolare [6, 2.2]	[6, 100.0]	[6, 100.0]	[0, 0.0]	[0, 0.0]
AVRT/vie accessorie [30, 11.0]	[30, 100.00]	[25, 83.3]	[0, 0.0]	[0, 0.0]

*=tamponamento

**=trombosi femorale

90,8%

Giaccardi et al JICE 2019 54:43-48. doi.org/10.1007/s10840-018-0390-7

EFFICACIA TERAPEUTICA

Meta-Analysis of Zero or Near-Zero Fluoroscopy Use during Ablation of Cardiac Arrhythmias

AUMENTO DEI TASSI DI SVILUPPO E DIFFUSIONE TECH

Globalization / The Wall Street Journal

A new electrophysiology era: zero fluoroscopy

Radiation exposure represents a concrete risk for both patients and medical staff. In the past few years, development of navigation systems have enabled a non-fluoroscopic approach to almost all right-sided and aortic retrograde left-sided ablations. On the basis of the limited experience of highly experienced centres, this approach seems to be well tolerated and effective. Moreover, procedural times are similar to those of conventional ablations. In the near future, the possibility of performing

... we strongly believe that reduction of fluoroscopy should be considered an ethical issue.

a transeptal puncture under electroanatomic non-fluoroscopic guidance avoid the risks in all routine electrophysiology activity. High costs and the lack of appropriate funding are the main obstacles to the diffusion of these techniques. However we strongly believe that reduction of fluoroscopy should be considered an ethical issue. The medical industry in order to reduce costs and educate physicians to facilitate the start of this new electrophysiology era.

LIMITATE RISORSE ECONOMICHE

I tumori in Italia

41mila €

Costo sociale annuo del tumore per l'unità di riferimento (paziente e care-giver)

si arriverebbe ad oltre 100mila euro l'anno se si aggiungesse il costo di un farmaco di nuova generazione (50-60 mila euro all'anno)

8 giorni

Durata media della degenza per il trattamento o indagini di neoplasie nel 2015

in diminuzione di circa un giorno rispetto al 2010.

In Italia la spesa per farmaci oncologici è quasi triplicata

passando da circa 1 mld di Euro nel 2007 a circa 3 mld nel 2014

Il costo attuale della terapia CAR-T si aggira sui 475.000/373.000 dollari

E questo è solo il costo netto del farmaco, al quale va aggiunto quello della sua somministrazione, dell'eventuale ricovero in terapia intensiva e dei farmaci usati per controllare gli effetti collaterali

Quanto possono costare i danni per esposizione alle radiazioni?

MEDIAMENTE UNA MALATTIA PROFESSIONALE COSTA ALL'ITALIA
OLTRE 200.000 EURO

I costi indiretti possono essere 5 volte superiori ai costi diretti (OSHA)

I tumori in Italia

DECESSI ATTRIBUIBILI A TUMORE

*In Italia il tumore
rappresenta ancora la
seconda causa di morte
dopo le malattie
cardiovascolari (37%)*

TUMORI EVITABILI

*grazie agli stili di vita
sani, all'applicazione delle
normative per il controllo
dei cancerogeni
ambientali e a screening*

La prevenzione dei tumori

2,9 €

Risparmio per cure mediche per ogni euro investito in prevenzione.

4,22%

In Italia per la prevenzione si spendono 5 miliardi di euro (2014).

Il tetto programmato stabilito nei Livelli Essenziali di Assistenza (LEA) invece è del 5%.

I fattori di rischio più comuni del cancro e cosa si può fare

- uso del tabacco
- essere sovrappeso o obesi e
- mancanza di attività fisica
- uso di alcool
- infezione da HPV a trasmissione sessuale
- infezione da epatite o altre infezioni virali
- **radiazioni ionizzanti**
- inquinamento atmosferico urbano
- fumo interno da uso domestico

**Ridurre l'esposizione alle radiazioni ionizzanti
(immagini diagnostiche professionali o mediche)**

LA DIRETTIVA 2013/59/EURATOM DEL CONSIGLIO EUROPEO DEL 5 DICEMBRE 2013

Le attività svolte contribuiscono a quel processo di ottimizzazione, rimarcato nella direttiva, che stabilisce, in sintesi, le norme fondamentali di sicurezza sulla protezione contro i pericoli derivanti dall'esposizione alle radiazioni ionizzanti, con specifici riferimenti alla diagnostica medica.

Near zero fluoroscopic exposure during catheter ablation of supraventricular arrhythmias: the NO-PARTY multicentre randomized trial

What's new?

- The radiation exposure during electrophysiology procedures is non-negligible for both patients and laboratory staff.
- The use of a minimally fluoroscopic approach (MFA) with the EnSite™NavX™ navigation system is associated with a significant reduction in total fluoroscopy time, patients' exposure, and operator radiation dose without any significant difference in terms of success and complication rates. The reduction in patients' exposure shows a 96% reduction in the estimated risks of cancer incidence and mortality and an important reduction in estimated years of life lost and years of life affected.
- The increase in life expectancy and in the period of cancer-free life makes the MFA economically affordable at a rough economical analysis. Thus, faced with such an advantage in terms of cancer prevention, it would be desirable that MFA procedures were increasingly performed, at least in young patients.

..... SENZA FILI

Parte debole del sistema: elettrocatereteri

Indicazioni:

1. FA bloccata in paziente fragile
2. MNSA con poca stimolazione prevista
3. Condizioni che precludono l'accesso venoso

..... SENZA FILI

The First Report on Communicating Leadless Anti-Tachycardia Pacemaker and Subcutaneous Implantable Defibrillator: The Next Step in Cardiac Rhythm Management ^{1,2} (Preclinical Study)

An episode of simulated VT (LV Pacing) followed by manually triggered S-ICD ATP command resulting in successful ATP-delivery by the LCP (10 beats, at 81% of coupling interval)

1. Tjong et al, AMC Heart Center, JACC Letters, <http://dx.doi.org/10.1016/j.jacc.2016.02.039>

2. Tjong et al, ACC2016, Moderated Poster Session, Forst Report on Communicating Antitachycardia Pacing-Enabled Leadless Pacemaker and Subcutaneous Implantable Defibrillator

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