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Radiation protection measures and sex distribution in European interventional catheterization laboratories: Results from the EAPCI Women's survey.

Short title: WEAPCI Radiation Survey

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Keywords: Gender issues; Radiation protection; Training and education

Abbreviations:
EAPCI: European Association of Percutaneous Cardiovascular Interventions

IC: Interventional Cardiologists

INTRODUCTION

From the previous survey performed by the European Association of Percutaneous Coronary Intervention Women's Committee (1), it appears that both women and men consider that the overall risk linked to radiation exposure hampers women from a career in interventional cardiology. Interventional car¬diologists (IC) are exposed at the highest levels registered amongst medical staff using x-rays(2).

Despite specific definition of the safe dose limit and protective strategies for the foetus (3)(4) (5) (6), the "risk of pregnancy" is often evoked as a reason for not pursuing an interventional career, or to justify the choices not to choose young women for a position. However, little is known about the current radiation-reducing strategies in European cathlabs (7).

Accordingly, the first aim of the 'EAPCI Women's Radiation Exposure and Regularities in European Catheterization Laboratories Survey' was to assess current practices on radiation protection and the second was to examine the sex ratio and practices during pregnancy.

METHODS

A web-based survey was developed by the EAPCI Women's committee (supplementary appendix 1).

RESULTS

The Survey was emailed to 1,065 cathlab directors on March 2016 (Supplementary Appendix 1).

Finally, 18 countries participated in the survey (Supplementary table 1).

Characteristics are described in Supplementary table 2. 97 centres had at least one radiological equipment older than 10 years, with a higher proportion (42.8%) in centres with more than three angiographic suites ($p = 0.006$).

Figure 1 shows the number and type of personal dosimeters and available radioprotective shielding. Active personal dosimeters were available in 48% of centres, with higher proportion in high volume PCI centres (difference 35.5%, $p<0.01$). Concerning radioprotective measures, cathlabs were well equipped with appropriate protective tools. The reporting frequency of radiation exposure was monthly in 39% of cases (Supplementary Figure 1). A medical follow up was scheduled in 80% of the centres, with one (29%) or two (36.5%) control visits per year with blood count (78.5%), thyroid function evaluation (61%) and eye examination (54%). Only a small percentage could state their cumulative and eye radiation dose for the past year (8% and 5%, respectively). 5% had never attended any educational program on radiation protection.

In more than one third of all catheterisation laboratories, none of the ICs were women. Female operators accounted for 18% (n=353) of 1,952 IC, with a similar proportion when considering a permanent position, whatever the type of institution. Cathlab director roles were held by females in 25 centres. Female fellows accounted for 24.5% (n=147) of the total 599 fellows ($p< 0.01$). Supplementary Figure 2 reported the distribution of physicians according to their age and sex.

The “risk of pregnancy” for 8% of directors has constituted a hindrance for a fellowship or permanent position. Nevertheless, work was allowed during pregnancy with radiation limits and adapted radiation protection equipment for 64 female physicians in 51 centres: for 14/53 in France, 2/147 in Italy, 9/11 UK and 3/4 in Denmark. Knowledge of the foetus dose limit was insufficient.

DISCUSSION

The main findings of the Survey are:

1) 29.7% of the radiological equipment is older than 10 years;

2) 2/3 of the physicians are wearing at least two dosimeters. The minimal radiation protection equipment is present.

3) IC is still predominantly a male sub-speciality

4) Local policies concerning work during pregnancy are very heterogeneous, even within each country.

The European Directive (3) has updated basic safety standards: the dose limit for eye lens has been lowered from 150 to 20mSv/year, and the recommended number of dosimeters is at least 2.

It has been suggested that no more than 10% of radiological equipment should be older than 10 years(8). Compared to the WIN Survey (7), we observed a larger reported use of lead glasses and table-suspended lead screen.

Current data do not suggest increased risks to the foetus (5), with a dose limit for the foetus of 1 mSv (3), with monthly monitoring of foetus dose (4-6) . Reproductive concerns have been also raised in interventional male physician (9). Nearly 60% of medical students worldwide are women, but women in cardiology still account for less than 20% (10, 11) with interventional cardiology remaining the lowest proportion. It has been shown that companies make more profit when workers and boards consist of both sexes (12). Cathlabs could benefit similarly from this.

LIMITATIONS

The survey was completed in 326 centres (30.6%).

CONCLUSIONS

ICs are the most exposed to ionising radiation. Newer strategies are available to reduce the radiation dose, improvement in awareness and follow up are crucial.

IMPACT ON DAILY PRACTICE

The Survey showed availability and use of minimal radiation protection tools, however less than 30% use lens dosimeter and less 10% know their level of radiation exposure. Sex disparity is still high, and evolution of the regulations upon pregnancy in the working environment seems possible.

Funding

None

Conflict of interest statement

None

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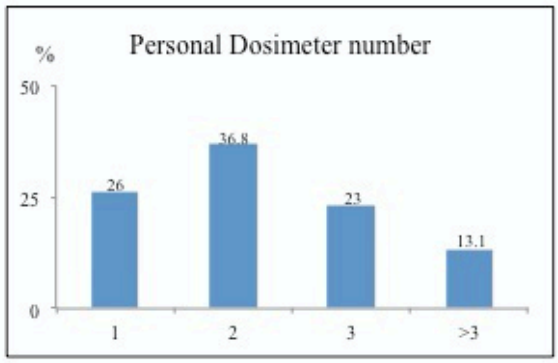
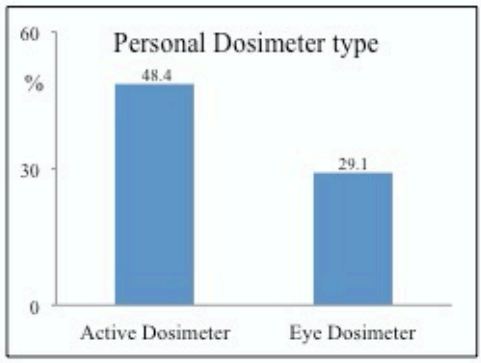
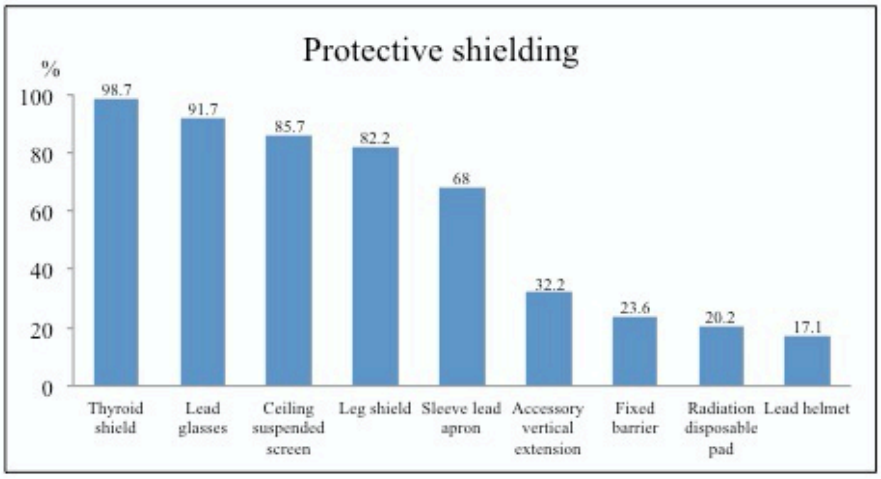
Figure 1: Number and type of personal dosimeters and available radioprotective shieldin







SUPPLEMENTARY MATERIALS

Appendix 1: Radiation Exposure and Regularities in European Catheterization Laboratories
an initiative of WOMEN-EAPCI Working Group

From the previous survey performed one year ago, it appears that both women and men consider that the burden of workload and the overall risk linked to radiation exposure hamper women from a career in interventional cardiology. Frequently, the "risk of a pregnancy" associated to young females cardiologists discourage catheterization laboratories directors to choose them for a fellowship and above all for a permanent position.

Recommended dose limits for occupational exposed personnel have been stated by ICRP publication103(International Commission on Radiological Protection (2007) The 2007 recom mendations of the International Commission on Radiological Protection. ICRP Publication 1 03. Ann ICRP 37:1– 332) and are the same for all European Nations, even if each Nation has the possibility to set more rigorous limits.

Concerning pregnancy, the ICRP Pubblication 117 (Rehani MM, Ciraj-Bjelac O, Vano E, Miller DL, Walsh S, Giordano BD et al.; International Commission on Radiological Protection. ICRP Publication 117. Radiological protection in fluoroscopically guided procedures performed outside the imaging department. Ann ICRP 2010;40:1–102) and the recent European Directive sets the dose limit for the foetus to 1 mSv (European Council. Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/ Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom. Official Journal of the European Union 2014;57:1–73.) and states that if a pregnant woman wishes to continue her job, a specific dosimeter at the level of the abdomen should be used with monthly monitoring of foetus dose and that adequate radiation safety measures must guarantee that this limit is not exceeded.

This limit is lower than the allowed doses in the USA, up to 5 mSv (measured by a waist dosimeter) for the entire pregnancy.

However local regulations for professionally exposed women workers also vary between countries.

Moreover, the latest reports on personnel radiation doses date back more than 10 years. Modern fluoroscopy machines as well as radiation protection strategies have evolved, as awareness among interventional community of potential stochastic and deterministic risks for patient and operator.

An updated assessment of the actual radiation doses appears necessary. Due to the huge discrepancy in sex ratio in interventional demography, it appears mandatory for the WOMEN group from the EAPCI to conduct a survey that could inform the everyday reality of these two points in European Catheterization Laboratories.

One of the purposes of this survey is to inquire gender ratio in direction of catheterization laboratories and medical and paramedical personals working in catheterization laboratories, know the proportion of coronary/ peripheral/structural and EPU procedures performed in European catheterization laboratories. The second aim is to assess real radiation exposure, protection, mean of measurement and educational program proposed and/or required as

well as the level of awareness about radiation protection. The real-life practice for pregnant cath-lab staff need also to be clarified.

Project organization:
Electronic questionnaire designed by WEAPCI and data base developed by ESC staff
Target individuals are directors (their representatives) of the catheterization laboratories
Members of WEAPCI act as national principal investigator monitoring the study performance

QUESTIONNAIRE

Part #1 – Catheterization laboratory structure

Institution (drop-down list – only 1 answer possible)

- ◊ Private clinic
- ◊ Public hospital
- ◊ University hospital

Number of catheterization rooms (drop-down list – only 1 answer possible)

- ◊ 1
- ◊ 2
- ◊ 3
- ◊ > 3

Type of the catheterization facilities (drop-down list – more answers possible)

- ◊ Philips
- ◊ Siemens
- ◊ GE
- ◊ others

Age of the oldest catheterization facility: _____years

Age of the newest catheterization facility: _____years

Catheterization Laboratory Director (drop-down list – only 1 answer possible)

- ◊ Male
- ◊ Female

Men physicians working in the catheterization laboratory:

- ◊ Number: _____
- ◊ Age range [min to max] _____ to _____ years
- ◊ Number of male fellows: ____
- ◊ Number of full time permanent position: ____

Women physician working in the catheterization laboratory:

- ◊ Number:__ __
- ◊ Age range [min to max] : ____ to ____ years
- ◊ Number of female fellows : ____
- ◊ Number of full time permanent position : ____

Non-medical personnel working in the catheterization laboratory:

- ◊ Number of men: ____
- ◊ Number of women: _____
- ◊ Radiologist technician: ____

Specific radiation safety person: (drop-down list – only 1 answer possible)

- ◊ yes
- ◊ no
- ◊ position not available

Number of procedures pro year (status 2016): ____

Of these procedures there are:

- ◊ Diagnostic coronary angiogramms: _____
- ◊ PCI:____
- ◊ Hemodynamic (right heart):____
- ◊ Structural (TAVI, mitraclip, PFO, LAAC) :____
- ◊ Peripheral :____
- ◊ Pediatric :____
- ◊ Electrophysiology :____

Does your catheterization laboratory operate 7/24h? (drop-down list – only 1 answer possible)

- ◊ yes
- ◊ yes, only during working days
- ◊ no

Part #2 – Radiation burden

Monitoring (passive): (drop-down list – only 1 answer possible)

- ◊ 1 dosimeter
- ◊ 2 dosimeters
- ◊ 3 dosimeters
- ◊ > 3 dosimeters

Positioning of dosimeters: (drop-down list – only 1 answer possible)

- ◊ Under the apron
- ◊ Outside of the apron
- ◊ Both

Personal dosimetry monitor (active) (drop-down list – only 1 answer possible)

- ◊ yes
- ◊ no

Dosimetry ring: (drop-down list – only 1 answer possible)

- ◊ yes
- ◊ no

Eyes dosimeter: (drop-down list – only 1 answer possible)

- ◊ yes
- ◊ no

Frequency of radiation exposure doses report: (drop-down list – only 1 answer possible)

- ◊ no
- ◊ yes, annual
- ◊ yes, biannual
- ◊ yes, less than annual

Report of the radiation exposure doses to the: (drop-down list – only 1 answer possible)

- ◊ director of catheterization laboratory
- ◊ director of the non-medical personal
- ◊ affected person
- ◊ person in charge of the radiation protection in the clinic
- ◊ all of them

Protection tools available in your catheterization laboratories: (drop-down list – more answers possible)

- ◊ Sleeveless lead apron
- ◊ Handle lead apron

◊ Thyroid shielding
◊ Lead glasses
◊ Ceiling suspended lead screens / upper body shield
◊ Protective lead curtains suspended from the side of the procedure table / lower body shield
◊ Accessory vertical extension
◊ Fixed barrier
◊ Lead helmet
◊ Lead door
◊ Radiation absorbing disposable pad
◊ Regular help for radiation reduction by dedicated key person with review of practice patterns

Part #3 – Radiation regularities for pregnant personal

Same for medical and non-medical personal: (drop-down list – only 1 answer possible)

- ◊ yes
- ◊ no

By law, work is totally forbidden in the cath lab: (drop-down list – only 1 answer possible)

- ◊ yes
- ◊ no

By use, any work totally forbidden in the cath lab: (drop-down list – only 1 answer possible)

- ◊ yes
- ◊ no

By law or use, work is allowed during full pregnancy with radiation limits: (drop-down list – only 1 answer possible)

- ◊ no
- ◊ yes at a limit of ____ mSv
- ◊ yes with adapted/modified radiation protection equipment

Number of pregnant physicians who worked in your cath lab during the last 5 year: ____

Number of pregnant non- medical staff who worked in your cath lab during the last 5 year: ____

Risk for pregnancy has been raised at least once in the last 5 years in the cath lab as a reason not to choose a candidate: (drop-down list – only 1 answer possible)

- ◊ no
- ◊ yes for a fellowship program
- ◊ yes for a permanent position

Risk for pregnancy has been raised at least once in past (> 5 years ago) in the cath lab as a reason not to choose a candidate: (drop-down list – only 1 answer possible)

- ◊ no
- ◊ yes, for a fellowship program
- ◊ yes, for a permanent position

Part #4 – Personal Information

Gender: (drop-down list – only 1 answer possible)

- ◊ Women
- ◊ Men

Age:____years old

Nation: (drop-down list)

Region: _____

ZIP code:_____

and if available national ID cath lab code: _____

Position: (drop-down list – only 1 answer possible)

- ◊ Professor
- ◊ Assistant professor
- ◊ Senior resident
- ◊ Resident
- ◊ Private consultant

Main activity: (drop-down list – only 1 answer possible)

- ◊ Interventional Cardiologist
- ◊ Electrophysiologist

Number of diagnostic coronary angiogram/year: (drop-down list – only 1 answer possible)

- ◊ none
- ◊ <50
- ◊ 50-100
- ◊ >100

Number of PCIs/year: (drop-down list – only 1 answer possible)

- ◊ none
- ◊ <50
- ◊ 50-100
- ◊ >100

Number of primary PCIs/year: (drop-down list – only 1 answer possible)

- ◊ none
- ◊ <30
- ◊ 31-50
- ◊ 51-75
- ◊ ≥75

Number of right heart catheterization/year: (drop-down list – only 1 answer possible)

- ◊ none
- ◊ <50
- ◊ 50-100
- ◊ >100

Number of structural interventions/year: (drop-down list – only 1 answer possible)

- ◊ none
- ◊ <30

- ◊ 31-50
- ◊ 51-75
- ◊ ≥75

Number of peripheral interventions/year: (drop-down list – only 1 answer possible)

- ◊ none
- ◊ <50
- ◊ 50-100
- ◊ >100

Number of pediatric procedures/year: (drop-down list – only 1 answer possible)

- ◊ none
- ◊ <50
- ◊ 50-100
- ◊ >100

Number of electrophysiology procedures/year:(drop-down list – only 1 answer possible)

- ◊ none
- ◊ <50
- ◊ 50-100
- ◊ >100

For how long are you self-ruling operator? ____years

Are you aware of your personal cumulative annual dose? (drop-down list – only 1 answer possible)

- ◊ no
- ◊ yes

If yes which is the value for the past year?: (NA in case of unknown values)

Annual Body dose: ____mSv
Annual Eyes dose: ____ mSv
Annual Hands dose:_ __mSv

Medical follow-up: **(**drop-down list – only 1 answer possible)

- ◊ no
- ◊ yes, once in a year
- ◊ yes, twice in a year
- ◊ yes, more than twice in a year
- ◊ yes, less than once a year

Do you have scheduled controls for: (more answers possible)

- ◊ Blood count
- ◊ Thyroid Function
- ◊ Lens opacity

Education/ training: (drop-down list – only 1 answer possible)

- ◊ Never done
- ◊ Optional
- ◊ Mandatory

Education/ training performed: (drop-down list – only 1 answer possible)

- ◊ During fellowship
- ◊ After fellowship
- ◊ Both during and after fellowship

If training validated the key message you have taken home is: (drop-down list – only 1 answer possible)

- ◊ Radiation is harmful
- ◊ Patient protection
- ◊ Operator protection
- ◊ Both are linked

Appendix 2 : DEFINITIONS

The active dosimeter is also called electronic, operational, alarm or DMC dosimeter. It provides a direct display of the accumulated dose as well as having some additional functions such as alarm threshold settings for dose or dose rate values. In addition it provides an audible and visual indication of the dose rate level. The dosimeter requires a battery to operate. This dosimeter is used for complementary dosimetry in the case of high radiation levels or for work and dose optimisation purposes.

The passive dosimeter is called 'passive' as it does not provide direct readouts and can operate without any active means. The reading is delayed.
Passive dosimeter at CERN is the personal, legal or DIS dosimeter.

High procedure volume cath lab: As the cath labs performing less than 400 PCI/year were the 10% of the centres (Moscucci M, Share D, Smith D, O'Donnell MJ, Riba A, McNamara R, Lalonde T, Defranco AC, Patel K, Kline Rogers E *et al*: **Relationship between operator volume and adverse outcome in contemporary percutaneous coronary intervention practice: an analysis of a quality-controlled multicenter percutaneous coronary intervention clinical database**. *J Am Coll Cardiol* 2005, **46**(4):625-632.), the threshold for low or high procedure volume cath lab was arbitrarily set on equal/less or more than 700 PCI/year in order to perform a comparison on survey topics.

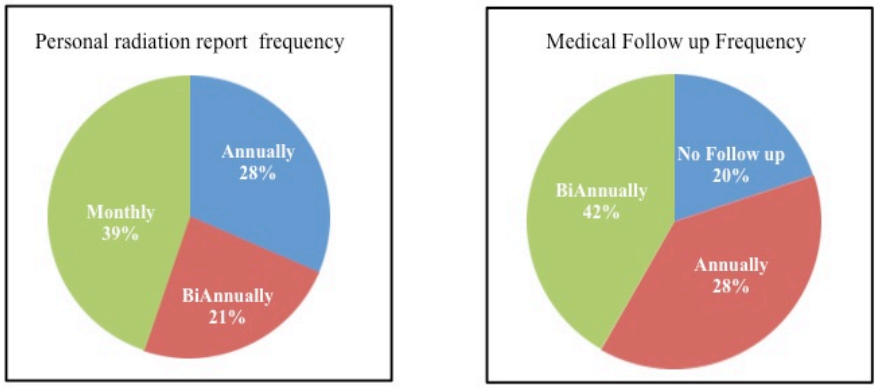
Supplementary table 1: Overview of survey responding cardiac catheterization laboratories

Responding Countries	Responding Cath lab	% of total cath lab
Belgium	9	19
Bosnia Herzegovina	1	17
Croatia	1	20
Cyprus	1	17
Denmark	4	80
France	53	26
Germany	33	7
Greece	2	4.
Israel	1	4
Italy	147	57
Poland	6	4
Portugal	2	7
Romania	1	5
Slovenia	1	20
Spain	22	21
Sweeden	29	94
UK	11	9
Other	3	NA

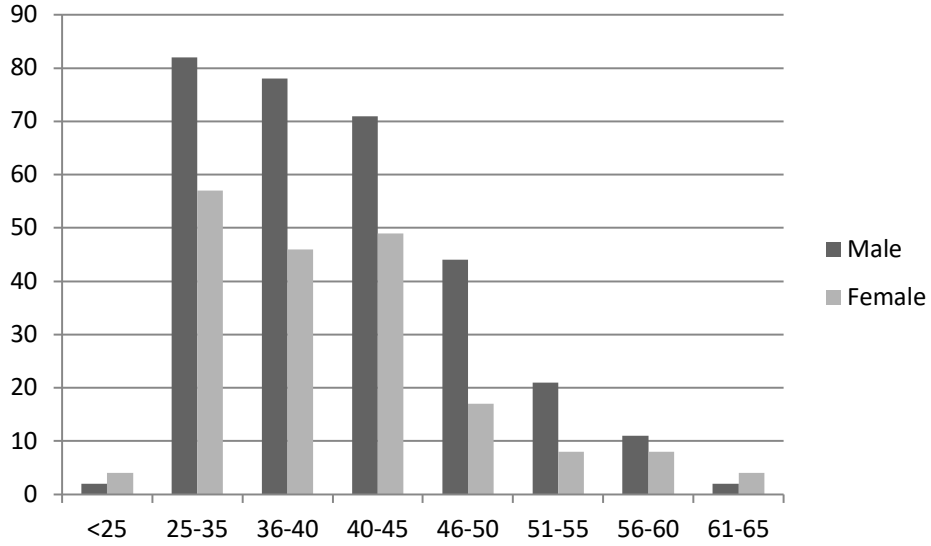
Supplementary table 2: Baseline Characteristics

	N (326)	%
Type of institution		
Public hospital	187	57.4
Private clinic	39	11.9
University hospital	93	28.5
Other	7	2.2
Number of Catheterisation rooms		
1	98	30
2	135	41
3	52	16
>3	35	10
24/24h 7/7 days activity		
Yes	301	92.3
No	19	5.9
Only during working days	6	1.8
Centres performing cardiovascular interventional procedures (n)		
PCI	323	99
Structural	206	63.2
Peripheral	147	45.1
Electrophysiology	134	41.1
Paediatric	43	13.2
Cardiovascular interventional procedures other than coronary angiogram (n)		
PCI	282348	73
Structural	21443	5.5
Peripheral	19917	5.1
Paediatric	6020	1.5
Electrophysiology	61963	16
Number of PCI per centre in 2016	33	10.1
<400	152	46.6
400-800	83	25.5
801-1200	58	17.8
>1200		
Centres with radiological equipment older than 10 years	97	29.7

Supplementary Figure 1: Personal dose report and frequency of medical follow up



Supplementary Figure 2: Demographic characteristics: number of physician according to sex and age



Appendix 4: Women EAPCI members

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