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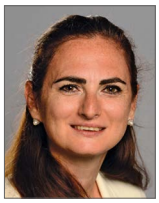
Radiation protection measures and sex distribution in European interventional catheterisation laboratories



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Introduction

From the previous survey performed by the European Association of Percutaneous Cardiovascular Interventions Women 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 cardiologists (IC) are exposed at the highest levels of radiation registered amongst medical staff using X-rays[2].

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

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

Perspectives, see page 24

Methods

A web-based survey was developed by the EAPCI Women Committee **(Supplementary Appendix 1, Supplementary Appendix 2)**.

Results

The survey was emailed to 1,065 cath lab directors in March 2016 **(Supplementary Appendix 1)**.

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

Baseline characteristics are shown in **Supplementary Table 2**. Ninety-seven centres had at least one item of 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 (see definition in **Supplementary Appendix 3**) were available in 48% of centres, with a higher proportion in high-volume PCI centres (difference 35.5%, p<0.01). Concerning radioprotective measures, cath labs were well equipped with appropriate protective tools.

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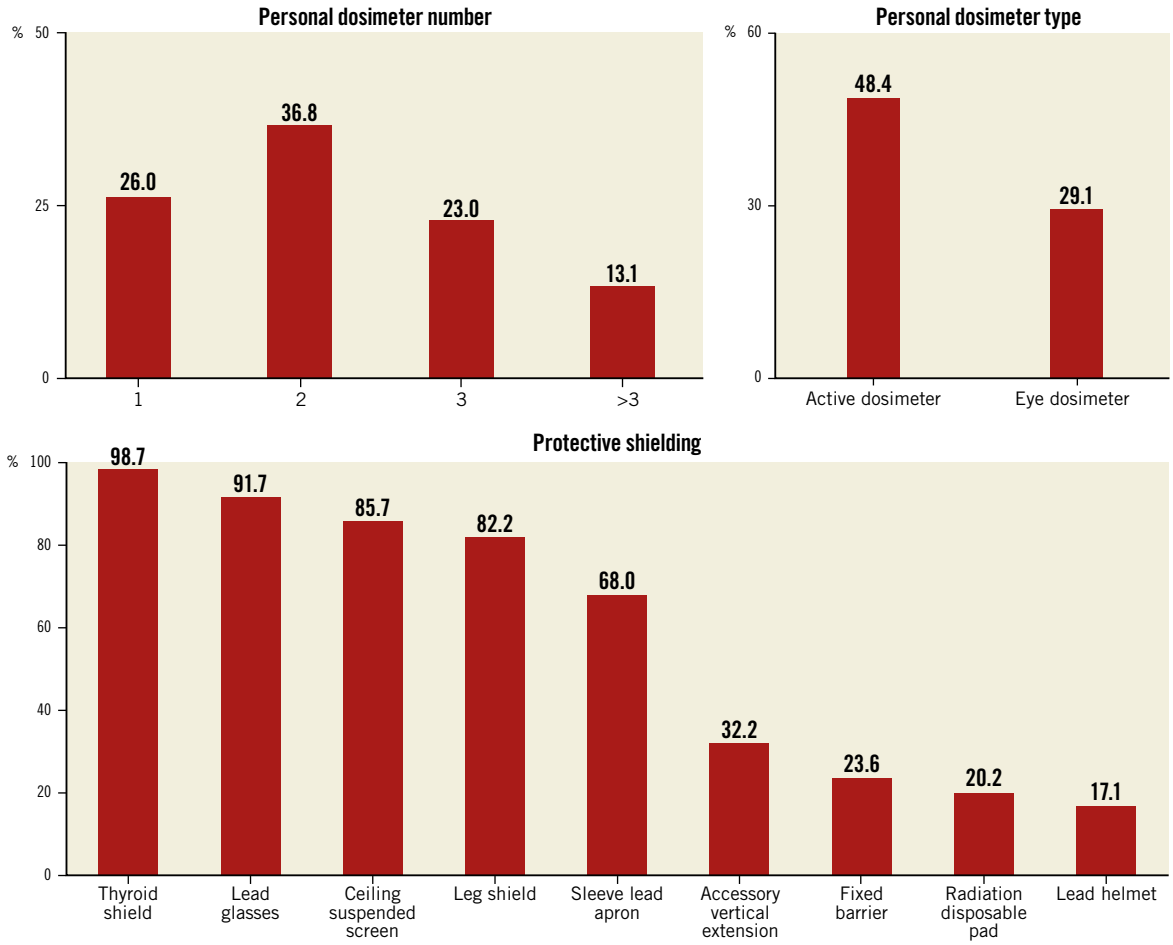

Figure 1. *Number and type of personal dosimeters and available radioprotective shielding.*

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 programme on radiation protection.

In more than one third of all catheterisation laboratories, none of the IC were women. Female operators accounted for 18% (n=353) of 1,952 IC, with a similar proportion whatever the type of institution: tertiary centre, public or private, or high- or low-volume centre. Cath lab 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** shows the distribution of physicians according to their age and sex.

For 8% of directors, the "risk of pregnancy" 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 as follows:

1) 29.7% of the radiological equipment is older than 10 years;
2) 2/3 of the physicians wear at least two dosimeters. The minimal radiation protection equipment is present;
3) Interventional cardiology 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 20 mSv/year, and the recommended number of dosimeters is at least two.

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 screens.

Current data do not suggest increased risks to the foetus[5], with a dose limit for the foetus of 1 mSv[3], and monthly monitoring of foetus dose[4-6]. Reproductive concerns have also been raised for interventional male physicians[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]. Cath labs could benefit similarly from this.

Limitations

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

Conclusions

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

Conflict of interest statement

The authors have no conflicts of interest to declare.

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Supplementary data

Supplementary Appendix 1. Radiation exposure and regularities in European catheterisation laboratories.

Supplementary Appendix 2. EAPCI Women members.

Supplementary Appendix 3. Definitions.

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

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

Supplementary Table 1. Overview of survey responding cardiac catheterisation laboratories.

Supplementary Table 2. Baseline characteristics.

The supplementary data are published online at: https://eurointervention.pcronline.com/doi/10.4244/EIJ-D-18-01044

Supplementary data

Supplementary Appendix 1. Radiation exposure and regularities in European catheterisation laboratories - an initiative of the EAPCI Women 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 with young female cardiologists discourages catheterisation laboratory directors from choosing them for a fellowship and above all for a permanent position.

Recommended dose limits for occupationally exposed personnel have been stated by ICRP publication 103 (International Commission on Radiological Protection [2007]. The 2007 recommendations of the International Commission on Radiological Protection. ICRP Publication 103. Ann ICRP. 2007;37:1-332) and are the same for all European nations, even if each nation has the possibility of setting more rigorous limits.

Concerning pregnancy, the ICRP Publication 117 (Rehani MM, Ciraj-Bjelac O, Vano E, Miller DL, Walsh S, Giordano BD, Persliden J; 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 set 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 state 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 among 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 increases among the interventional community of potential stochastic and deterministic risks for patient and operator.

An updated assessment of the actual radiation doses appeared necessary. Due to the huge discrepancy in sex ratio in interventional demography, it appeared mandatory for the Women Group from the EAPCI to conduct a survey that could inform the everyday reality of these two points in European catheterisation laboratories.

One of the purposes of this survey was to inquire into the gender ratio in the direction of catheterisation laboratories and medical and paramedical personnel working in catheterisation laboratories, and to know the proportion of coronary/peripheral/structural and EPU procedures performed in European catheterisation laboratories. The second aim was to assess real radiation exposure, protection, means of measurement and educational programme proposed and/or required as well as the level of awareness about radiation protection. The real-life practice for pregnant cath lab staff also needed to be clarified.

Project organisation

An electronic questionnaire was designed by WEAPCI and a database developed by ESC staff. Target individuals were the directors (or their representatives) of the catheterisation laboratories.

Members of WEAPCI acted as national principal investigators 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

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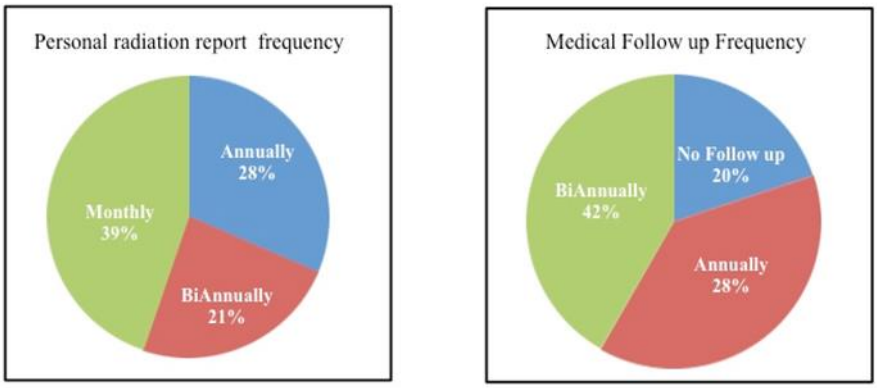
Supplementary Appendix 3. Definitions

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.

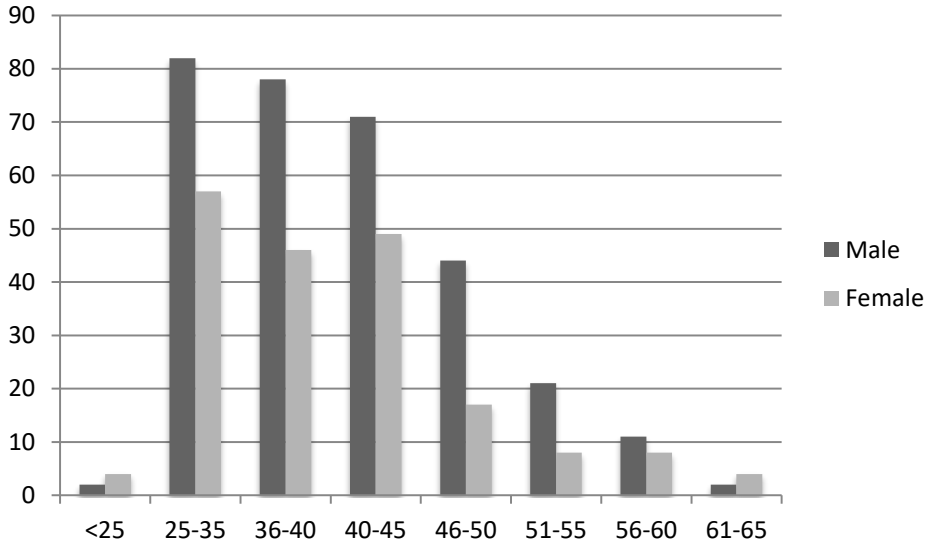
The passive dosimeter is called "passive" as it does not provide direct readouts and can operate without any active means. The reading is delayed.

Passive dosimeter at CERN is the personal, legal or DIS dosimeter.

High procedure volume cath lab: as the cath labs performing fewer than 400 PCI/year represented 10% of the centres[13], the threshold for a low or high procedure volume cath lab was arbitrarily set at equal to/less or more than 700 PCI/year in order to perform a comparison on survey topics.



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



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

Supplementary Table 1. Overview of survey responding cardiac catheterisation laboratories.

Responding countries	Responding cath labs	% of total cath labs
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
Sweden	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
24/24 hrs 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	282,348	73
Structural	21,443	5.5
Peripheral	19,917	5.1
Paediatric	6,020	1.5
Electrophysiology	61,963	16
Number of PCIs per centre in 2016		
<400	33	10.1
400-800	152	46.6
801-1,200	83	25.5
>1,200	58	17.8
Centres with radiological equipment older than 10 years	97	29.7