Clinical Research

The France PCI registry: Design, methodology and key findings[☆]

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ARTICLE INFO

SUMMARY

Background: Obstructive coronary artery disease is the main cause of death worldwide. By tracking events and gaining feedback on patient management, the most relevant information is provided to public health services to further improve prognosis.

Aims: To create an inclusive and accurate registry of all percutaneous coronary intervention (PCI) procedures performed in France, to assess and improve the quality of care and create research incentives. Also, to describe the methodology of this French national registry of interventional cardiology, and present early key findings.

Methods: The France PCI registry is a multicentre observational registry that includes consecutive patients undergoing coronary angiography and/or PCI. The registry was set up to provide online data analysis and structured reports of PCI activity, including process of care measures and assessment of risk-adjusted outcomes in all French PCI centres that are willing to participate. More than 150 baseline data items, describing demographic status, PCI indications and techniques, and in-hospital and 1-year outcomes, are captured into local reporting software by medical doctors and local research technicians, with subsequent encryption and internet transfer to central data servers. Annual activity reports and scoring tools available on the France PCI website enable users to benchmark and improve clinical practices. External validation and consistency assessments are performed, with feedback of data completeness to centres.

Results: Between 01 January 2014 and 31 December 2022, participating centres increased from six to 47, and collected 364,770 invasive coronary angiograms and 176,030 PCIs, including 54,049 non-ST-segment elevation myocardial infarction cases and 31,631 ST-segment elevation myocardial infarction cases. Fifteen studies stemming from the France PCI registry have already been published.

Conclusions: This fully electronic, daily updated, high-quality, low-cost, national registry is sustainable, and is now expanding. Merging with medicoeconomic databases and nested randomized scientific studies are ongoing steps to expand its scientific potential.

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Abbreviations

ARS	Agence Régionale de Santé
COVID-19	coronavirus disease 2019
GACI	Groupe Athérome coronaire et Cardiologie Interventionnelle
ICA	invasive coronary angiography
MACE	major adverse cardiovascular events
NCDR	National Cardiovascular Data Registry
NSTEMI	non-ST-segment elevation myocardial infarction
PCI	percutaneous coronary intervention
SCAAR	Swedish Coronary Angiogram and Angioplasty Registry
SFC	Société Française de Cardiologie
STEMI	ST-segment elevation myocardial infarction
SNDS	Système National des Données de Santé

Background

Obstructive coronary artery disease is the main cause of death worldwide [1], particularly in emerging countries. By tracking events and gaining feedback on patient management, the most relevant information is provided to public health services to further improve prognosis [2]. Invasive coronary angiography (ICA) and percutaneous coronary intervention (PCI) are the key procedures for the diagnosis and treatment of obstructive coronary artery disease, and the gateways for exhaustive coronary artery disease registries worldwide. The ultimate goal of these surveys is to achieve high and sustainable quality data, but this is rarely accomplished [3]. In 2014, the French Centre-Val de Loire region launched a multicentre, fully integrated, low-cost, self-supported registry. Early reports on ST-segment elevation myocardial infarction (STEMI) pathways in this rural area demonstrated the feasibility of a high-quality local dataset, which became the basis for the national France PCI registry that now comprises more than one quarter of French percutaneous coronary intervention (PCI) centres [4]. Our main objectives are to describe how the national France PCI project was launched and the early key findings, and to discuss the project's sustainability and perspectives.

Methods

Study design and participants

The France PCI registry is a multicentre, observational, ongoing registry of consecutive patients undergoing coronary angiography and/or PCI. The registry was launched on 01 January 2014 in the Centre-Val de Loire region (CRAC registry), and is now expanding to all the French territories, with 47 PCI centres involved. Participants aged <18 years and lack of consent are the only exclusion criteria.

Study organization

Participating centres and participants

All centres with an on-site 24-hour primary PCI service have been invited to join the France PCI registry, pending on-site interfaced reporting software (CardioReport [MediReport, Paris, France], Hemolia [Clinityx, Boulogne-Billancourt, France], Atout Coeur [Altilog, Caen, France]) and clinical research facilities for data monitoring and patient follow-up. All consecutive patients undergoing diagnostic ICA and or PCI are eligible for enrolment. PCI is defined as when any coronary device is used to treat a coronary lesion.

Recruitment and data collection

Calibrated interfaces have been set up with manufacturers to allow automatic data collection. Inclusion in the registry is the sole responsibility of each local principal investigator.

Up to 150 data items are collected for each patient, including preadmission setting with time delays for primary PCI, demographics characteristics, risk factors, medical history, clinical presentation, procedural data and medical treatments. Data on low-density lipoprotein and glycated haemoglobin have also been collected since 2021 (Fig. A.1 and Table A.1). All data definitions are listed in Appendix B. Data are subsequently encrypted and transferred via internet to a secured national database website. Data monitoring, reporting and extraction are supervised by the coordinating Clinical Research Associate and a National Medical Coordinator.

Clinical follow-up

Participant follow-up is the responsibility of the local on-site Research Technician at each participating centre. Medications and major adverse events (MACE), defined as the composite of death, stent thrombosis (Academic Research Consortium-2 definition), myocardial infarction (European Society of Cardiology definition), unplanned coronary revascularization, major bleeding (Bleeding Academic Research Consortium ≥ 3 definition) and stroke, are assessed at 1 year.

Data quality control and completeness

Local monitoring is carried out by an on-site Clinical Research Associate, who assesses data completion, answers queries and collects participants' follow-up data. A permanent full-time Clinical Research Coordinator (one full-time coordinator for 10 participant centres) performs central monitoring, quality control and coordination of the local Clinical Research Associates. On-site reporting software allows all consecutive diagnostic angiography and PCI procedures to be captured. Less than 2% of patients declined participation in our early experience (CRAC registry) [4].

Red-coloured identification of the data registry, pop-up error messages during reporting and specific France PCI tabs are used to improve data completeness. Exhaustivity reached 99.6% [4]. Data reliability is evaluated during reporting by the cross-check of 110 critical data items for each procedure via dedicated monitoring

tools (79 for consistency and 85 for exhaustivity). A first evaluation made in the CRAC registry demonstrated a high level of consistency of 89%.

In-hospital data are extracted from the hospital case report form within 2 weeks of discharge. Follow-up data are obtained at 1 year by telephone interview, captured by the on-site Clinical Research Associate on a dedicated tab in the on-site report software, and automatically transferred to a central database. Each MACE is validated by the local PCI centre.

Predefined queries are generated automatically by the monitoring tools of the central website by the Clinical Research Coordinator, and are sent back to each site for evaluation. Remote quality controls are performed every 2 months (Fig. A.2), and data monitoring is finalized within the next 4 months of data capture; the data are then ready for scientific analyses. Yearly on-site external audits are performed at each participant centre by the Clinical Research Coordinator, to check the list of withdrawals and the patient information process, and to evaluate data monitoring.

Database access and centre feedback

The France PCI website was created by MediReport, and data are stored on Microsoft Azure®. The database is upgraded daily and pseudonymized, with no patient or physician identification. A unique identification procedure and patient key are created to merge data from the website to the electronic case report form (on-site reporting software), allowing central remote monitoring.

Each centre has direct online access to its own local dataset, with immediate feedback via activity reports, and online comparison with regional or national anonymous pooled data results. For example, the rate of radial access, radiation dose (personal dosimetry service)/procedure and rate of stent thrombosis at 1 year are accessible online, allowing benchmarking for all participating centres. A scoring tool on 10 quality indicators, including relevance, safety, performance and data quality, allows confidential self-evaluation and subsequent potential improvement (Table 1). In addition, exhaustive annual national and regional reports are published on the France PCI registry website [5].

Ethics

France PCI is registered at ClinicalTrials.org (identifier: NCT02778724) and is conducted according to contemporary clinical practice guidelines and French regulations (Advisory Committee on Information Processing in Material Research in the Field of Health, no.13.245). The French Persons Protection Committee (IRB00003888) approved the study protocol (no. 15–231). Data file collection and storage were approved by the Commission Nationale de l'Informatique et des Libertés (CNIL; no. 2014–073), and all participants are informed about data collection and the aims of the survey.

Promotion and fundings

The France PCI registry is promoted by the non-profit organization "Association France PCI". The steering committee comprised founders and past presidents of the Groupe Athérome coronaire et Cardiologie Interventionnelle (GACI), the French professional organization of interventional cardiologists. France PCI is also supported by the Société Française de Cardiologie (SFC), the Conseil National Professionnel Cardio-Vasculaire (CNPCV) and the European Association of Percutaneous Cardiovascular Interventions (EAPCI) (Fig. A.3). The scientific committee is elected by the steering committee, and is composed of interventional cardiology representatives of different regions, to periodically evaluate and provide guidance for all scientific works generated by the database.

The clinical cardiac research unit of Les Hôpitaux de Chartres is the Clinical Research Organization mandated to plan, coordinate, execute and supervise the processes involved in the development of the registry; it is composed of a medical coordinator, a project manager, a data manager, a central Clinical Research Associate and a secretary.

Up to 2019, the France PCI registry was exclusively supported by institutional grants from the French Health Ministry, regional health agencies (Agence Régionale de Santé [ARS] Centre-Val de Loire, ARS Normandie, ARS, Auvergne-Rhône-Alpes) and a dozen health establishments. Private grants have supported the France PCI registry since 2018, but sponsors were not involved in the study design, data collection and management, data analyses and interpretation, or in the preparation, review and approval of manuscripts. This full e-registry, without double capture and automatic monitoring, limits substantial operating costs, which are evaluated to be € 16/procedure (as found in the CRAC registry [4], and are mostly accounted for by the human resources needed for monitoring and management.

Statistical analysis

To compare helicopter transfer versus ground transport of patients with STEMI, bivariate analysis was carried out. Student's t test or the Mann-Whitney-Wilcoxon test was used for continuous variables, according to the nature of variable distribution (Gaussian or not). Simple logistic regression was used for the primary endpoint. Statistical analysis was performed with SAS software, version 9.4 (SAS Institute, Cary, NC, USA). $P < 0.05$ was considered statistically significant.

Results

Between 01 January 2014 and 31 December 2022, participating centres increased from six to 47, including 17 general hospitals, seven academic hospitals, 20 private clinics and three private not-profit clinics, representing one out of four centres in France (Fig. 1). All PCI centres of Centre-Val de Loire and Normandie are now involved, and 40 additional centres are expected to be recruited by the end of 2023. This very active registry has led to 15 international publications (Table A.2), and we are providing the key findings.

Number of participants and key trends

On 31 December 2022, the France PCI database collected 364,770 ICAs and 176,030 PCIs, including 54,049 cases of non-STEMI and 31,631 cases of STEMI (Fig. 2). In the six participating centres of the Centre-Val de Loire region, a substantial increase in the number of PCIs, driven by stable angina and silent ischaemia, has been observed since 2014 – a surprising finding, given the lack of evidence of any clinical benefit of PCI for chronic coronary syndrome (Fig. 3). In the same cohort, between 2014 and 2021, the 30-day mortality rate after PCI varied from 4.2% to 3.7% in myocardial infarction, and from 0.9% to 0.6% in stable angina (Fig. 4).

Key timelines

Early local experience: prehospital STEMI transfer in rural areas

This study was undertaken in the first six centres of the Centre-Val de Loire region. Helicopter transfer of patients with STEMI who were eligible for primary PCI in a French rural area was found to be associated with an increase in the delay from first medical contact to primary PCI versus ground transportation: 137 minutes (95% confidence interval 110–181 minutes) vs 103 minutes (95% confidence interval 80–135 minutes) ($P < 0.0001$). This difference was magnified for distances of < 50 km from the PCI hospital. As

Table 1
Quality indicators and scoring (2022).

		CCS				STEMI<24h				PCI				Safety (coronary angiogram)				Data Quality			
		No documented ischemia		Ambulatory		Delay ECG-PCI STEMI<24h		CV rehab		Radial access (ST+exclused)		FFR		Contrast		PDS		Exhaustivity Hospital F-U		Lost patient (N-1)	
	Score /10	P.cent		P.cent		Min		P.cent		P.cent		P.cent		MI		cGy cm2		Taux		P.cent	
National avg	5	39,2 %		17,5 %		91		49,7 %		90,4 %		8,6 %		75		1 738,12		91,77		3,9 %	
N°Centre	score total	%	Note	%	Note	Min	Note	%	Note	%	Note	%	Note	MI	Note	cGy cm2	Note	%	Note	%	Note
1	9	20,3 %	🟢	60,7 %	🟢	108	🔴	62,0 %	🟢	96,0 %	🟢	14,8 %	🟢	68	🟢	1 496,50	🟢	99,89	🟢	1,9 %	🟢
3	7	32,3 %	🟢	5,0 %	🔴	98	🔴	74,7 %	🟢	94,3 %	🟢	6,5 %	🔴	57	🟢	1 110,71	🟢	99,66	🟢	0,8 %	🟢
4	8	29,9 %	🟢	25,1 %	🟢	95	🔴	65,3 %	🟢	93,4 %	🟢	13,1 %	🟢	65	🟢	1 864,53	🔴	99,82	🟢	1,8 %	🟢
5	3	43,6 %	🔴	1,7 %	🔴	100	🔴	73,0 %	🟢	94,0 %	🟢	11,8 %	🟢	80	🔴	2 117,60	🔴	75,02	🔴	2,5 %	🟢
8	5	39,4 %	🔴	2,5 %	🔴	108	🔴	24,6 %	🔴	94,3 %	🟢	6,1 %	🔴	49	🟢	904,21	🟢	82,82	🔴	0,2 %	🟢
9	5	48,8 %	🔴	38,5 %	🟢	115	🔴	42,7 %	🔴	92,9 %	🟢	0,5 %	🔴	57	🟢	1 422,18	🟢	73,31	🔴	1,5 %	🟢
10	4	48,5 %	🔴	44,2 %	🟢	89	🟢	43,2 %	🔴	85,4 %	🔴	7,0 %	🔴	83	🔴	2 251,22	🔴	100,00	🟢	0,3 %	🟢
13	10	18,2 %	🟢	31,0 %	🟢	85	🟢	89,3 %	🟢	92,1 %	🟢	10,6 %	🟢	67	🟢	1 607,65	🟢	99,48	🟢		🟢
14	5	43,5 %	🔴	10,3 %	🔴	94	🔴	74,2 %	🟢	91,7 %	🟢	7,2 %	🔴	68	🟢	1 799,44	🔴	93,58	🟢	0,3 %	🟢
15	6	40,1 %	🔴	1,1 %	🔴	105	🔴	74,2 %	🟢	94,6 %	🟢	12,3 %	🟢	72	🟢	1 179,72	🟢	100,00	🟢	8,2 %	🔴
16	10	38,1 %	🟢	70,8 %	🟢	88	🟢	75,4 %	🟢	97,4 %	🟢	12,2 %	🟢	64	🟢	1 252,03	🟢	100,00	🟢	1,8 %	🟢
17	9	27,9 %	🟢	33,2 %	🟢	73	🟢	73,8 %	🟢	90,6 %	🟢	11,1 %	🟢	52	🟢	1 459,02	🟢	100,00	🟢	4,7 %	🔴
18	3	21,4 %	🟢	6,3 %	🔴	107	🔴	31,2 %	🔴	94,3 %	🟢	2,4 %	🔴	125	🔴	2 350,87	🔴	96,05	🟢	19,9 %	🔴
19	4	41,1 %	🔴	4,8 %	🔴	104	🔴	57,7 %	🟢	90,3 %	🔴	8,0 %	🔴	64	🟢	1 513,78	🟢	99,15	🟢	4,9 %	🔴
21	7	39,1 %	🟢	2,7 %	🔴	93	🔴	55,1 %	🟢	94,5 %	🟢	5,1 %	🔴	63	🟢	1 195,14	🟢	98,18	🟢	1,1 %	🟢
22	4	31,5 %	🟢	2,2 %	🔴	75	🟢	13,9 %	🔴	94,7 %	🟢	1,3 %	🔴	68	🟢	2 617,41	🔴	75,77	🔴	6,3 %	🔴
23	4	41,7 %	🔴	16,8 %	🔴	100	🔴	57,9 %	🟢	94,4 %	🟢	8,4 %	🔴	83	🔴	1 468,49	🟢	99,95	🟢	3,8 %	🟢
24	4	29,7 %	🟢	5,7 %	🔴	88	🟢	6,4 %	🔴	81,4 %	🔴	15,1 %	🟢	105	🔴	2 310,23	🔴	100,00	🟢	2,2 %	🟢
25	8	33,0 %	🟢	17,9 %	🟢	65	🟢	65,6 %	🟢	94,3 %	🟢	12,3 %	🟢	59	🟢	1 658,70	🟢	69,64	🔴	0,6 %	🟢
26	6	36,8 %	🟢	39,1 %	🟢	74	🟢	45,5 %	🔴	91,8 %	🟢	22,5 %	🟢	83	🔴	1 743,98	🔴	86,61	🔴	7,5 %	🔴
27	5	29,3 %	🟢	2,7 %	🔴	90	🟢	57,1 %	🟢	86,4 %	🔴	10,1 %	🟢	90	🔴	2 200,83	🔴	99,60	🟢	4,1 %	🔴
28	5	54,9 %	🔴	0,2 %	🔴	82	🟢	30,9 %	🔴	85,1 %	🔴	2,0 %	🔴	58	🟢	1 509,70	🟢	99,79	🟢	0,8 %	🟢
29	5	33,9 %	🟢	2,6 %	🔴	78	🟢	41,5 %	🔴	89,2 %	🔴	15,9 %	🟢	95	🔴	2 765,08	🔴	95,63	🟢		🟢
31	6	57,2 %	🔴	7,5 %	🔴	90	🟢	31,7 %	🔴	91,6 %	🟢	9,2 %	🟢	52	🟢	1 509,41	🟢	73,61	🔴		🟢
32	3	50,3 %	🔴	4,0 %	🔴	66	🟢	11,2 %	🔴	92,7 %	🟢	7,7 %	🔴	87	🔴	2 502,16	🔴	99,40	🟢	24,8 %	🔴
33	4	46,7 %	🔴	0,4 %	🔴	98	🔴	59,7 %	🟢	95,2 %	🟢	7,5 %	🔴	82	🔴	1 672,13	🟢	100,00	🟢	14,6 %	🔴
34	4	39,3 %	🔴	11,8 %	🔴	68	🟢	31,3 %	🔴	56,1 %	🔴	13,6 %	🟢	135	🔴	2 868,02	🔴	97,55	🟢	6,5 %	🔴
35	9	21,4 %	🟢	23,5 %	🟢	85	🟢	68,9 %	🟢	95,9 %	🟢	19,7 %	🟢	65	🟢	955,52	🟢	98,41	🟢	2,6 %	🟢
36	5	43,0 %	🔴	2,5 %	🔴	83	🟢	40,6 %	🔴	92,5 %	🟢	12,7 %	🟢	85	🔴	1 474,96	🟢	99,43	🟢	8,5 %	🔴
37	2	49,5 %	🔴	25,9 %	🟢	65	🟢	16,0 %	🔴	86,9 %	🔴	1,6 %	🔴	75	🟢	2 440,45	🔴	90,02	🔴	2,9 %	🟢
39	4	47,5 %	🔴	10,3 %	🔴	87	🟢	31,5 %	🔴	95,3 %	🟢	8,5 %	🔴	69	🟢	1 736,66	🟢	79,12	🔴		🟧
40	4	25,3 %	🟢	1,1 %	🔴	110	🔴	22,1 %	🔴	64,3 %	🔴	17,3 %	🟢	91	🔴	1 098,70	🟢	99,77	🟢		🟧
42	4	15,7 %	🟢	2,1 %	🔴	140	🔴	21,1 %	🔴	93,4 %	🟢	11,5 %	🟢	65	🟢	2 097,86	🔴	67,21	🔴		🟧
43	6	30,2 %	🟢	23,1 %	🟢	94	🔴	41,2 %	🔴	95,8 %	🟢	10,4 %	🟢	81	🔴	1 201,35	🟢	95,38	🟢		🟧
44	6	55,9 %	🔴	42,8 %	🟢	87	🟢	26,6 %	🔴	95,4 %	🟢	5,3 %	🔴	50	🟢	731,28	🟢	98,28	🟢		🟧
46	5	39,2 %	🟢	4,2 %	🔴	100	🔴	75,4 %	🟢	97,4 %	🟢	18,4 %	🟢	78	🔴	1 809,27	🔴	100,00	🟢		🟧
47	5	32,8 %	🟢	72,4 %	🟢	89	🟢	17,7 %	🔴	84,3 %	🔴	11,5 %	🟢	91	🔴	1 906,14	🔴	98,16	🟢		🟧
48	5	49,9 %	🔴	18,1 %	🟢	78	🟢	64,7 %	🟢	74,4 %	🔴	2,3 %	🔴	78	🔴	880,09	🟢	99,91	🟢		🟧
49	3	0,0 %	🟢		🔴		🟢		🔴		🔴		🔴	80	🔴	2 482,84	🔴		🟢		🟢
50	3	33,1 %	🟢	7,1 %	🔴	96	🔴	48,2 %	🔴	89,8 %	🔴	3,3 %	🔴	69	🟢	1 521,43	🟢	87,15	🔴		🟧
51	4	44,0 %	🔴	7,5 %	🔴	50	🟢	34,8 %	🔴	92,4 %	🟢	5,1 %	🔴	55	🟢	1 729,53	🟢	74,69	🔴		🟧
52	6	11,9 %	🟢		🔴	71	🟢	54,6 %	🟢	96,0 %	🟢	4,1 %	🔴	74	🟢	2 034,27	🔴	99,52	🟢		🟧
53	7	32,6 %	🟢	1,8 %	🔴	92	🔴	58,1 %	🟢	91,1 %	🟢	8,7 %	🟢	71	🟢	1 617,19	🟢	72,58	🔴		🟢

Each France PCI centre can check in real time the evolution of pre-established quality indicators, and compare themselves with other centres. A score of one point per indicator (green light) is assigned if the centre's result is equal to or better than the national average. A score of zero points per indicator (red light) is assigned if the centre's result is less than the national average. The sum of the results leads to an overall score (out of 10) for the centre, which quickly identifies indicators to be improved. An orange light indicates data not available. 24 h: 24 hours; CCS: chronic coronary syndrome; cGy: centigray; CV: cardiovascular; ECG: electrocardiogram; FFR: fractional flow reserve; F-U: follow-up; MI: myocardial infarction; Min: minutes; P.cent: percent; PCI: percutaneous coronary intervention; PDS: personal dosimetry service; ST: stent thrombosis; STEMI: ST-segment elevation myocardial infarction.
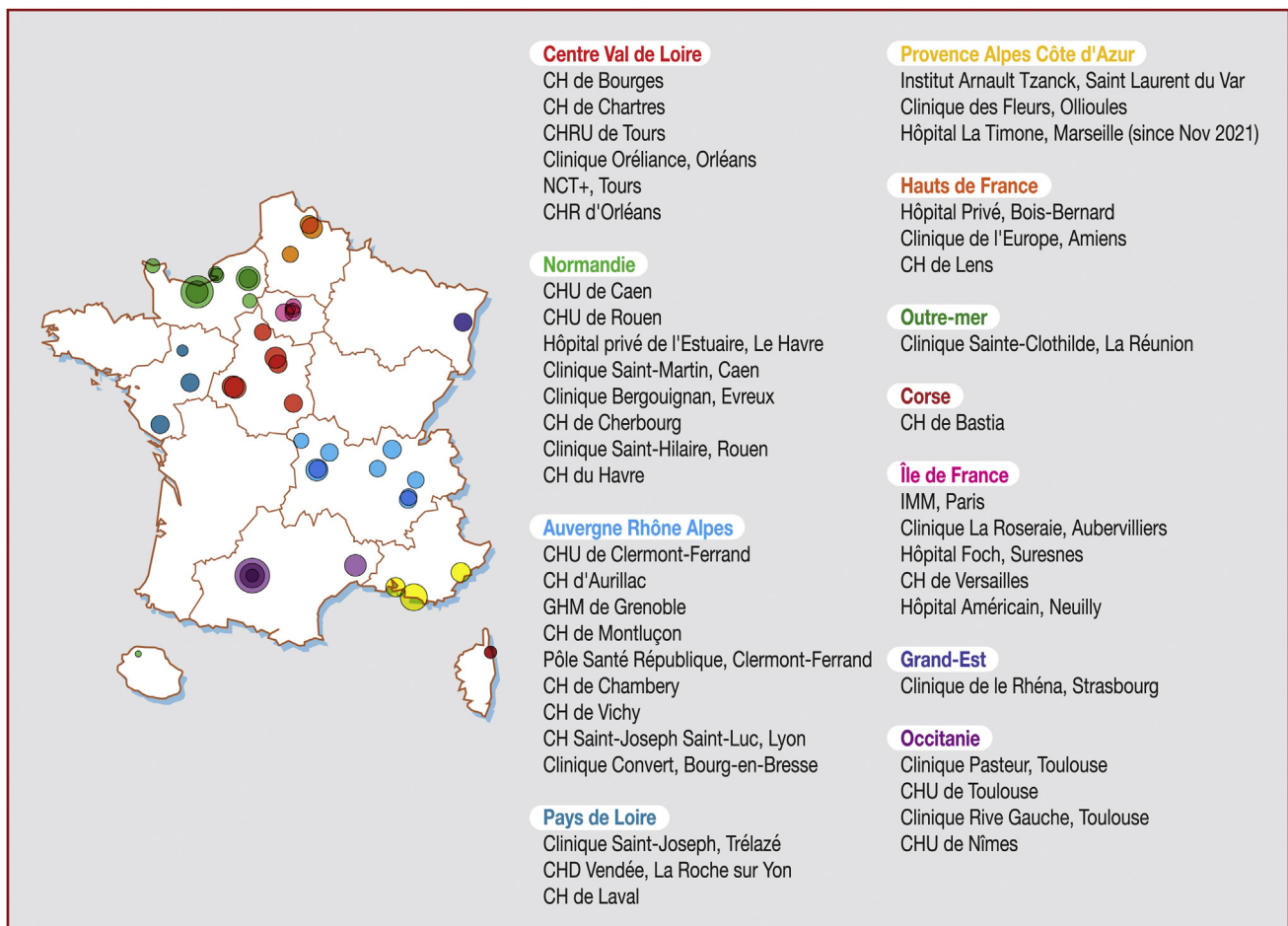
Figure 1. A quarter of French percutaneous coronary intervention (PCI) centres are participating in the France PCI registry in 2022, and this is expected to increase to 50% by the end of 2023. CH: Centre Hospitalier; CHD: Centre Hospitalier Départemental; CHR: Centre Hospitalier Régional; CHRU: Centre Hospitalier Régional Universitaire; CHU: Centre Hospitalier Universitaire; GHM: Groupe Hospitalier Mutualiste; IMM: Institut Mutualiste Montsouris; NCT: Nouvelle Clinique Tourangelle.

a consequence, total ischaemic time was increased (261 minutes [95% confidence interval 190–395 minutes] vs 195 minutes [95% confidence interval 146–300 minutes]; $P < 0.0001$), as was cost, suggesting that helicopter transportation should not be considered as the goal standard [6].

Regional survey during the coronavirus disease 2019 (COVID-19) pandemic

This study was undertaken in western France PCI centres during the COVID-19 outbreak, and was among the first to demonstrate a significant decline in patients with STEMI undergoing primary PCI, with a longer transfer time for patients who presented directly to the emergency department [7,8] and a significantly increased mortality (doubled). At that time, the pandemic activity was low in this area, and there were only a few eastern PCI centres in the France PCI registry.

Nationwide study: Clinical impact of fractional flow reserve-guided versus angiography-guided PCI

France PCI has also demonstrated a significant reduction in major clinical events (−30%) and all cause 1-year mortality (−64%) in fractional flow reserve-guided PCI ($n = 1259$) versus angiography-guided PCI ($n = 13,125$) among participants with chronic coronary syndrome. This finding is consistent with the Swedish (Swedish Coronary Angiogram and Angioplasty Registry [SCAAR]), Chinese and American (Clinical Assessment Reporting

and Tracking [CART]) registries [9–12], and is supportive of the implementation of fractional flow reserve when ischaemia is not documented.

Discussion

Study objectives

The main objectives of the national France PCI registry are to provide a description of the participants with coronary artery disease who undergo invasive management, to evaluate the implementation of practice guidelines, to keep track of clinical practices over time, to detect the consequences of major health crises early, to provide a comprehensive self-evaluation tool for each participating centre and to allow research projects at local and national levels.

Obtaining a sustainable high-quality national registry for coronary disease is a major goal of all cardiovascular guidelines, to monitor patterns of care, healthcare effectiveness and safety, and to improve clinical outcomes [13]. Numerous experiences have been launched into this venture, and some have been operational for more than 20 years, such as the National Cardiovascular Data Registry (NCDR; USA), the British Cardiovascular Intervention Society (BCIS; UK), the Japanese PCI registry (Japan) and SCAAR (Sweden) [14–17]. Standardized data collection, integrated tools for rapid feedback to participating centres, electronic data capture (with plausibility controls and highlighting of incorrectly entered data),
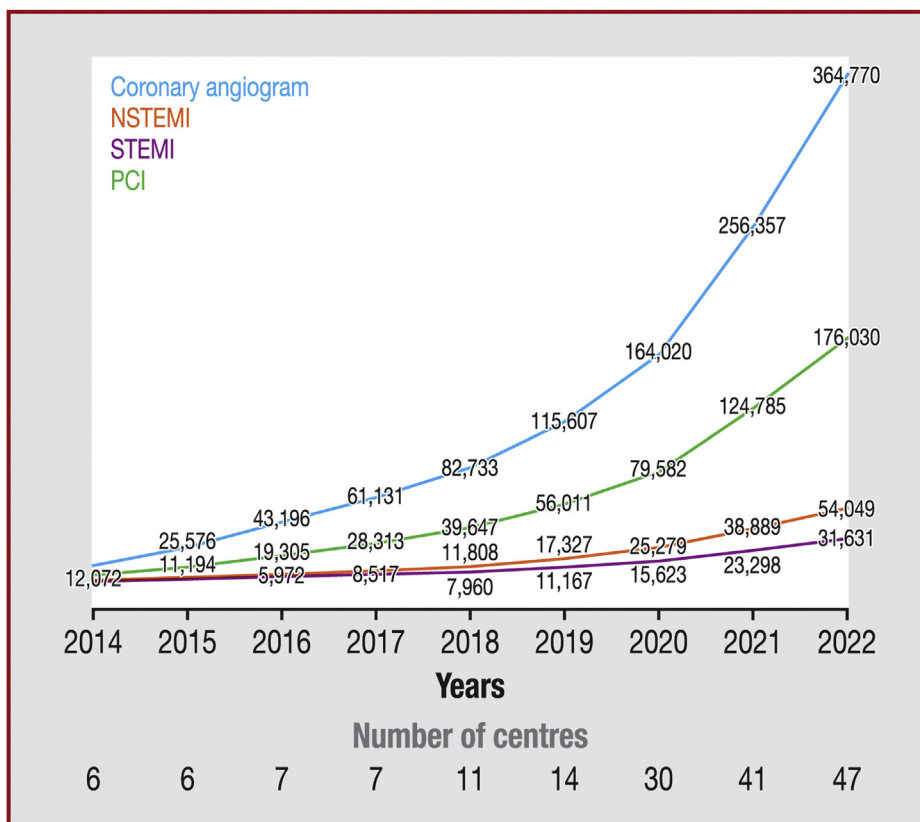
Figure 2. Trends in invasive coronary angiography and percutaneous coronary intervention (PCI), according to clinical status, in the France PCI registry, between 2014 and 2022. PCI for stable coronary artery disease represents only 55% of PCIs. NSTEMI: non-ST-segment elevation myocardial infarction; STEMI: ST-segment elevation myocardial infarction.
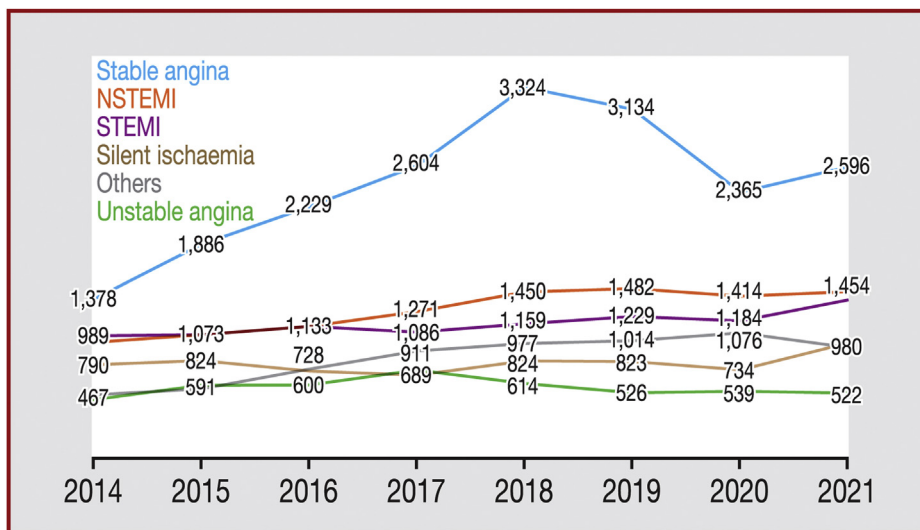

Figure 3. Number of percutaneous coronary interventions (PCIs), according to clinical presentation, in the Centre-Val de Loire (CVL) region. Stable coronary artery disease remains the most predominant reason for PCI, and is the most striking finding. NSTEMI: non-ST-segment elevation myocardial infarction; STEMI: ST-segment elevation myocardial infarction.

consecutive enrolment of patients for representativity and reporting of all collected data are the mandatory conditions for successful and sustainable surveys [18].

A previous aborted attempt to create a national French PCI registry inspired the France PCI team to build an original methodology for a sustainable project [19]. First, this includes high-quality data collection, with systematic remote monitoring and on-site personnel provision. Second, an easy and friendly interface with low constraints is needed to ensure centre adherence. Third,

providing rapid feedback with self-evaluation tools is essential at the level of each participating centre [20–22]. Fourth, cutting cost-expenditure is another essential goal. Human resources for follow-up and monitoring are the guarantee of data quality, but represent 80% of the registry's budget. We have evaluated a cost per procedure of € 16, one of the lowest compared with the NCDR ($ 248 estimated/procedure) or *a fortiori* with a randomized study (€ 26,000/patient) [23,24]. Fifth, all involved participants should be convinced that it is a gainful project. Health establishments
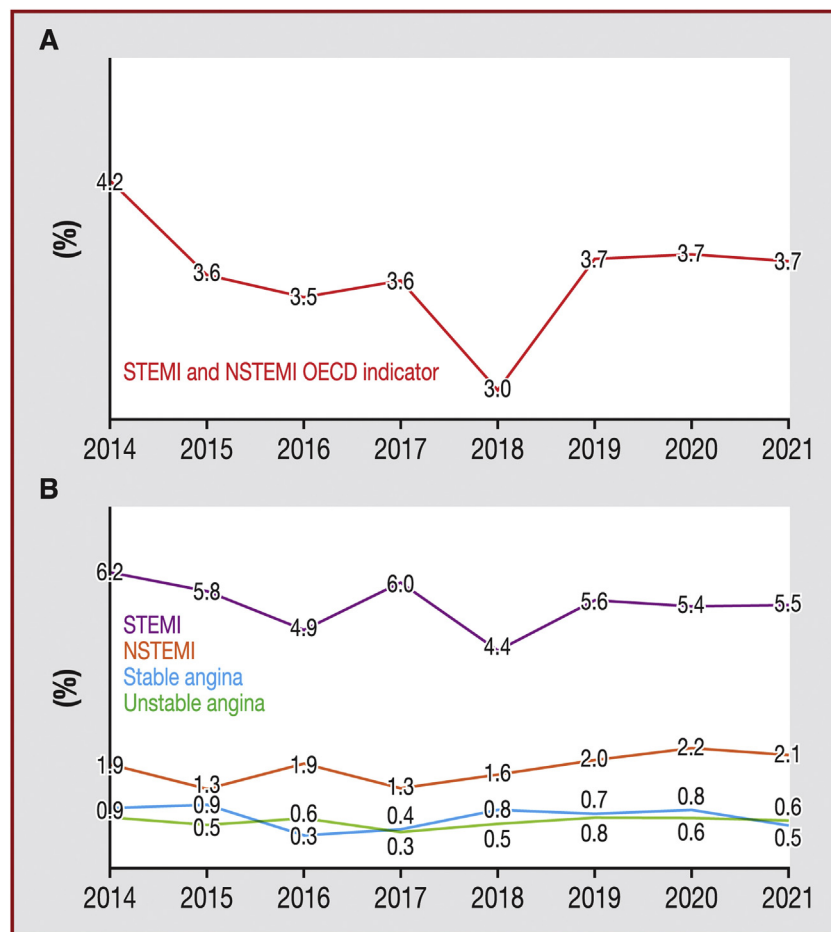
Figure 4. One-month mortality after percutaneous coronary intervention (PCI), according to clinical presentation, in the France PCI registry. NSTEMI: non-ST-segment elevation myocardial infarction; OECD: Organisation for Economic Cooperation and Development (Organisation de coopération et de développement économiques); STEMI: ST-segment elevation myocardial infarction.

should embrace such a project, which provides quality indicator assessment with subsequent improvement in quality of care and creates incentives for local research projects. Health authorities need reliable online data for epidemiological or medicoeconomic studies, planning care offers, health alerts and assessment of care relevance delivered by interventional cardiologists, with the goal of improving quality of care and patient prognosis. Ten quality indicators have been discussed, selected and ranked by the France PCI scientific committee (Table 1). Dedicated queries have been set up, so that quality indicators can be assessed directly by each centre and compared with the global survey.
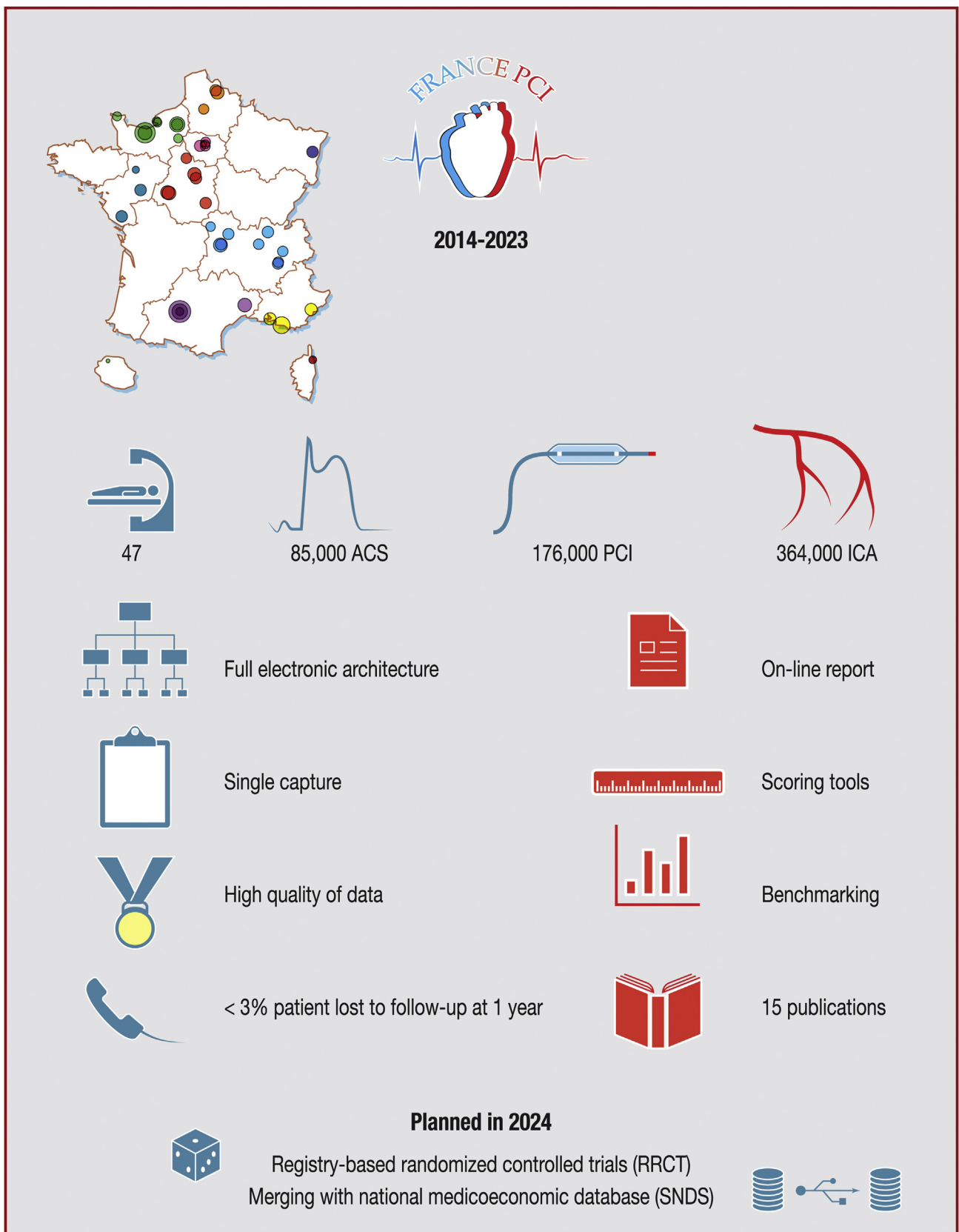
What are the future perspectives?

Involving patients as active participants in the long-term follow-up process is a key step and can be achieved by the use of connected web applications. Our aim is to cut down time-consuming phone calls for participant follow-up to < 20% [25]. Matching our registry with medicoadministrative databases (Système National des Données de Santé [SNDS]), including the patient's vital status (Centre d'Épidémiologie sur les Causes Médicales de Décès [CépiDC]), procedures and hospitalization (Programme de Médicalisation des Systèmes d'Information [PMSI]) or treatments (Caisse Primaire d'Assurance Maladie [CPAM]), via a health data hub is the second goal. This should allow long-term mortality and medication follow-up beyond 1 year, without significant additional cost. Expansion to all 200 French PCI centres should be achieved within the coming years, with the consistent support of the local ARS, which may

trigger aggregation of all French regions by 2027. By this time, the France PCI project will have become an exhaustive nationwide registry, although it is already representative of the French PCI population. The all-electronic architecture of the registry should pave the way for nested randomized trials, as has already been done in SCAAR [26]. This mega database may also be used as an efficient tool to predict cardiovascular events, with the help of artificial intelligence and machine learning, and also acts as a whistleblower for the medical authorities. This was demonstrated during the COVID-19 pandemic and may happen again with fractional flow reserve utilization as a result of its positive impact on 1-year survival in the stable PCI population in our registry. Diagnostic approach is a fast-moving field, and non-invasive imaging tools are now being considered as first-line approaches. We are therefore considering adding coronary computed tomography angiography within the survey, as its use grows each year.

Conclusions

France PCI is a contemporary national registry for interventional cardiology; its fully automated electronic architecture, with a dedicated onsite clinical research supply, yields a high-quality, low-cost, daily updated database. In addition, online scoring tools allow comparison, objective evaluation and improvement of clinical practice in all participating centres. In the future, merging the France PCI registry with medicoeconomic databases will enable long-term follow-up and expansion of data collection, which may pave the way for nested randomized scientific studies (Central illustration).

Central illustration. France PCI. ACS: acute coronary syndrome; F-U: follow-up; ICA: invasive coronary angiography; PCI: percutaneous coronary intervention; RRCT: registry-based randomized controlled trial; SNDS: Système National des Données de Santé.

Sources of funding

Acknowledgments

Disclosure of interest

The authors declare that they have no competing interest.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at https://doi.org/10.1016/j.acvd.2023.08.005.

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