The QERMID Belgian PCI registry

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Introduction and Study material

The Belgian working group on interventional cardiology (BWGIC) of the Belgian society of cardiology took the initiative to collect data from percutaneous coronary interventions (PCIs) since 1996. Collection of clinically relevant data was done by fax in the first years, then in a web-database hosted by the European society of cardiology from 2006 to 2012. This database allowed extensive peer review and benchmarking between Belgian and European centers.

Since March 2012, health authorities decided to move the registration of PCI data to QERMID (Quality oriented Electronic Registration of Medical Implant Devices) as a condition for reimbursement. Although the clinical dataset was similar to that of the previous database, no fusion of data was done and all information gathered before and after March 2012 remained separated in two different databases. Additionally, no access to the QERMID data was allowed to the medical community during the first 3 years which was a source of incomprehension and frustration for the BWGIC and for the college of cardiology whose missions include quality control and promotion of good clinical practice. Finally, access to source data was provided in 2016, on the form of 5 excel tables containing anonymous data from 104789 PCIs performed in Belgium between March 1st 2012 and March 31st 2016. These tables contained all information encoded by Belgian PCI centers, such as clinical status, PCI indication, procedural data and hospital outcome; in addition, survival status or date of death was provided by the national registry (BCSS) for each individual patient living in Belgium.

Methods

The tables containing source data were imported in a new database to allow creation of specific queries: in the present report, we compared the clinical characteristics and the outcome of patients treated in 2015 in the 28 PCI centers with a long-lasting experience in interventional cardiology with those of patients treated during the same period in the 21 PCI

centers having obtained agreement after 2012. Analysis of patients' characteristics and outcome was limited to the patients for whom BCSS info is available.

Results

In 3 years, the number of belgian cardiology centers allowed to perform PCIs has increased by 50% from 33 in 2013 to 49 in 2015. Simultaneously, the number of PCIs raised by 12%, from 24139 to 26985 and the number of operators increased in a similar proportion from 193 to 219. This increase followed a long period of stability during which both the number of cathlabs and of PCIs had remained remarkably stable. Consequently, the mean annual workload decreased from 731 to 551 PCIs per center and remained stable (from 125 to 123) per operator with a wide range.

Ischemic status and clinical characteristics

The analysis was intentionally limited to the 26382 patients (98%) for whom survival status is available in the BCSS. Stable angina and acute coronary syndromes (ACS) were almost equally represented as the initial cause of PCI but the proportion of ACS was significantly higher in the 21 newly approved (new) PCI centers than in the 28 centers with an agreement > 3 years (historical ; table 1). A small number of patients had an additional PCI during the same hospital stay; among those, staged planned PCIs were more frequent in new centers while redo PCIs for recurrence of ischemia or complications were equally represented in new and in historical centers. The characteristics of patients treated for stable angina or for (ACS) are listed in table 2. The only significant difference between both types of PCI centers is a higher proportion of renal failures in stable patients treated in historical centers. Age, gender and other comorbidities are almost identical.

Among the patients reported in stable condition at the time of PCI, a positive ECG stress test was the most frequently reported proof of ischemia (overall: 39%). Other imaging or functional tests were less frequent, each accounting for less than 8% of indications.

Interestingly, 39% of PCIs performed in stable patients were done without such testing or based on resting ECG only.

Outcome

Overall in-hospital and 30-days mortality were identical in new (respectively 2.50% and 3.44%) and in historical (respectively: 2.42 and 3.09%) PCI centers with an important dispersion among centers in each group. As expected, both in-hospital and 30-days mortalities were higher when PCI was done for ACS than for stable angina. Considering separately these 2 groups of indications, the only significant difference is a higher mortality between hospital discharge and the 30^{th} day in new versus historical centers (figure 1).

Data entered in the QERMID database do not allow distinguishing CABG performed urgently for failure or complication of PCI from staged or hybrid procedures. CABG performed the day of PCI are rare but significantly more frequent in historical centers, the difference becoming insignificant when the delay is extended to “same or next day” or “same week” (figure 2).

Discussion

Changes in the conditions for agreement of new interventional cardiology centers that occurred in 2012 considerably impacted the Belgian landscape of invasive cardiology. Within two consecutive years, 21 new centers obtained an agreement to perform PCI, accounting for 22% of total PCI activity in 2015. Consequently, the mean workload per center decreased considerably and cases were redistributed among centers and operators with various levels of expertise.

Our analysis of the 2015 PCI data as entered in the QERMID database only shows minimal differences in patients’ characteristics, indication, documentation of ischemia and outcome between new and historical PCI centers, considered as two homogenous groups. Although reassuring, these findings should not lead us to underestimate the heterogeneity of individual performance among centers in each group and the possible negative effects of dilution of experience and competition in patients’ recruitment. Further analysis taking into

account the comorbidities susceptible to influence patients' outcome could help to identify the influence of centers performance on patients' outcome and the impact of this new policy on the quality of care.

Limitations of the PCI QERMID registry are well known: the dataset is limited, particularly for clinical parameters and for complications and the information is based on reporting by the centers without systematic on-site monitoring. Although previous peer-reviews of PCI centers have shown a good concordance between source documents and data entered in the database, these controls were limited to a fraction of the population; a more systematic validation of entries should be required, would these data be exploited for public reporting or in an optic of "pay for quality".

Figure legends

Figure 1:

In-hospital and 30-days mortality after PCI in stable patients and in patients with ACS in newly approved PCI center (in green) and in historical PCI centers (in blue). Bars represent 30-days mortality as the addition of in-hospital mortality (in dark green or blue) with mortality between discharge and day 30 (in light green or blue).

Figure 2:

Percentage of CABG performed same day, same or next day or within 1 week (same week)after PCI in newly approved PCI center (in green) and in historical PCI centers (in blue). P values refer to differences between both types of sites.

Table 1. Ischemic status of patients

		21 newly approved PCI centers	28 PCI centers with agreement > 3 years
Total PCI, n		5750	20632
Initial PCI, n	Stable	2853 (50)	11127 (54) *
	ACS (including STEMI)	2769 (48)	9182 (44) *
Additional PCI during same hospital stay, n	Staged (stable)	94 (1.6)	197 (0.95) *
	Redo for recurrence of ischemia or complication	34 (0.6)	126 (0.6)

* $p<0.01$ vs new centers

Table 2. Population characteristics

		21 newly approved PCI centers	28 PCI centers with agreement > 3 years
Stable	Age (yrs±SD)	68±11	68±11
	Female gender, n (%)	749 (26.3)	2936 (26.4)
	Diabetes, n (%)	759 (26.6)	2967 (26.7)
	Renal failure, n (%)	114 (4.0)	665 (6.0) *
	Previous stroke , n (%)	99 (3.5)	400 (3.6)
ACS	Age (yrs±SD)	67±13	66±13
	Female gender, n (%)	760 (27.5)	2392 (26.1)
	Diabetes, n (%)	633 (22.9)	2027 (22.1)
	Renal failure , n (%)	163 (5.9)	572 (6.2)
	Previous stroke , n (%)	106 (3.8)	344 (3.8)

* $p<0.01$ vs new centers

Figure 1

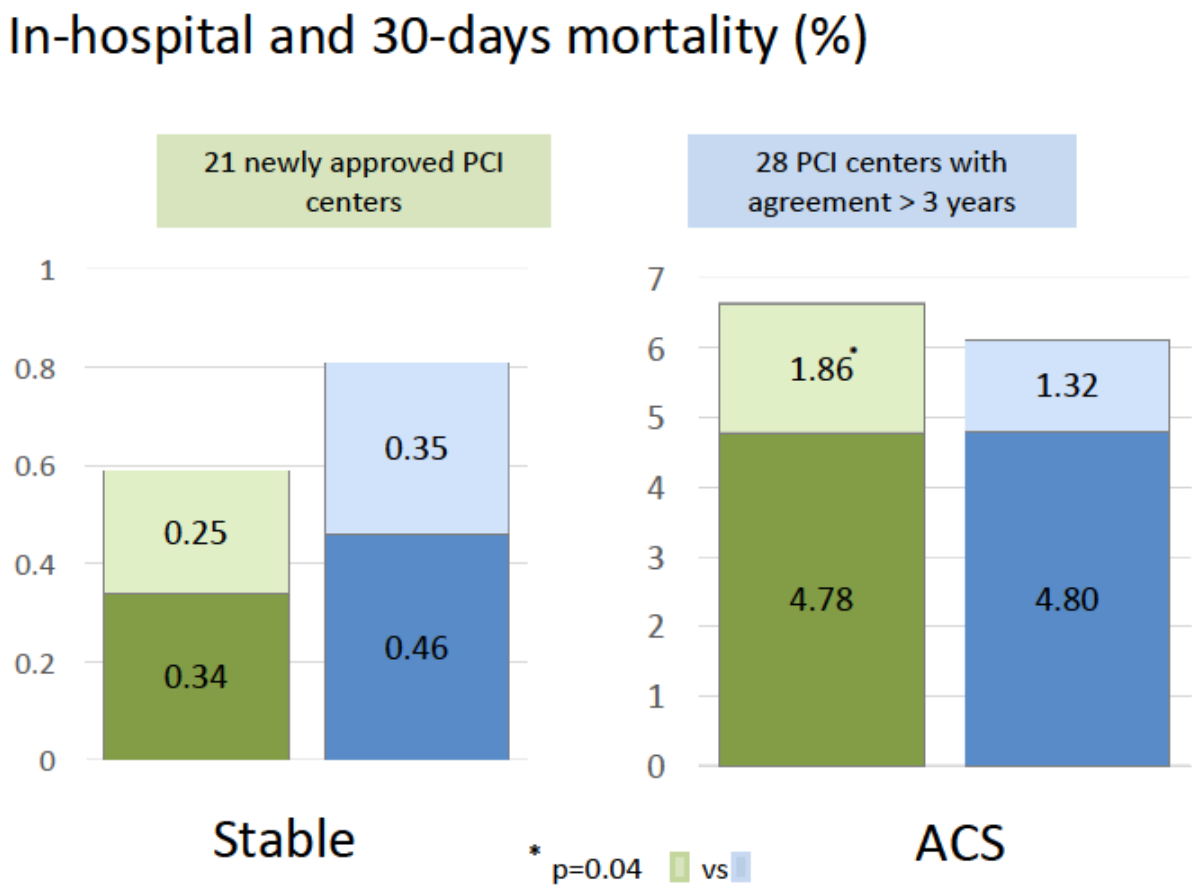
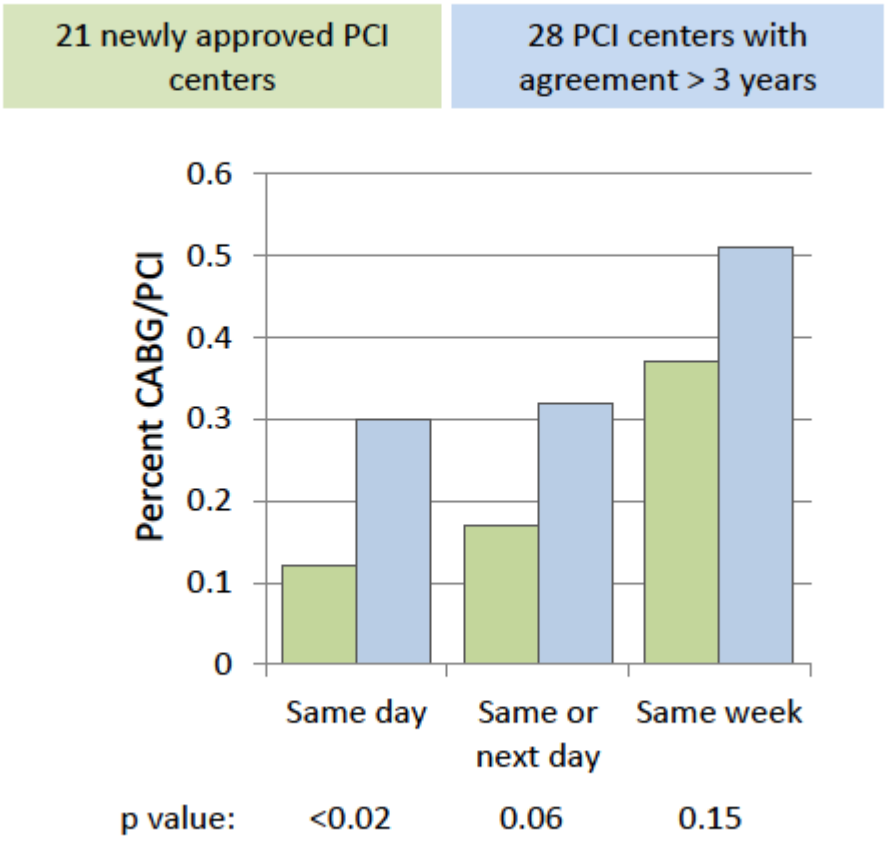

In-hospital and 30-days mortality (%)
21 newly approved PCI centers
28 PCI centers with agreement > 3 years
1
0.8
0.6
0.4
0.2
0
0.25
0.34
0.35
0.46
7
6
5
4
3
2
1
0
1.86
4.78
1.32
4.80
Stable
ACS
* p=0.04
vs

Figure 2.


21 newly approved PCI centers
28 PCI centers with agreement > 3 years
Percent CABG/PCI
0.6
0.5
0.4
0.3
0.2
0.1
0
Same day
Same or next day
Same week
p value:
<0.02
0.06
0.15