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# Contemporary Use of Post-Dilatation for Stent Optimization During Percutaneous Coronary Intervention; Results From the Netherlands Heart Registration

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## ABSTRACT

**Backgrounds:** Post-dilatation after stenting with a non-compliant (NC) balloon can be used to improve overall percutaneous coronary intervention (PCI) result. Due to lack of evidence on the effect of post-dilatation on adverse clinical endpoints there is no consensus whether post-dilatation should be used routinely. The aim of the current study was to determine the contemporary practice of post-dilatation.

**Methods:** This study included patients from the Netherlands Heart Registration who underwent PCI between the 4th quarter of 2020 and the 3rd quarter of 2021. The primary endpoint was the rate of post-dilatation with a NC balloon. Secondary endpoints included differences in baseline and procedural characteristics of patients that received post-dilatation and patients that did not receive post-dilatation.

**Results:** Out of 12,960 patients from 11 hospitals, 49.9% underwent post-dilatation. There was a variety in post-dilatation between hospitals ranging from 29.3% to 82.7% and among operators ranging from 15.9% to 90.5%. Post-dilatation was used less frequent in patients presenting with ST-elevation myocardial infarction or out of hospital cardiac arrest. Multivessel and left main PCI, long stent length and use of intracoronary imaging and calcium modification were associated with increased use of post-dilatation. When imaging was used, the percentage of post-dilatation was 79.4%.

**Abbreviations:** IVUS, intravascular ultrasound; LM, left main; NC, non-compliant; NHR, Netherlands Heart Registration; OCT, optimal coherence tomography; PCI, percutaneous coronary intervention.

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**Conclusions:** In the Netherlands, stent optimization with post-dilatation using NC balloon is performed in only half of the patients undergoing PCI, with variations in frequency across centres and operators. Post-dilatation is more often used in cases of complex PCI and when intracoronary imaging or calcium modification techniques are used.

## 1 | Introduction

Stent underexpansion and stent strut malapposition are important predictors for stent thrombosis (ST) and in-stent restenosis (ISR), following percutaneous coronary intervention (PCI) [1]. Therefore, achieving an optimal stent result is paramount in mitigating adverse events post-PCI. Invasive coronary angiography (ICA) has inherent limitations in accurately assessing vessel dimensions, calcium burden, circumferential tissue and whether a stent has achieved full expansion [2]. Therefore, use of ICA alone is insufficient for guiding stent optimization.

The limitations of ICA could be overcome by using additional guidance from digital stent enhancement and intracoronary imaging. In particular intracoronary imaging has gained increasing evidence, supporting its utility for PCI guidance in recent years [3]. One of its benefits is the capability to identify untreated residual disease and stent under-expansion, a phenomenon observed in a significant proportion of stented coronaries [4]. Consequently, imaging often leads to additional stenting and post-dilatation with high-pressure non-compliant (NC) balloons to achieve full lesion coverage, increase stent expansion and reduce strut malapposition. Despite the advantages of intracoronary imaging, its adoption in daily practice remains low and is usually reserved for more complex coronary lesions, as intracoronary imaging increases procedural time and costs. There are limited studies that have explored the effect of routine use of post-dilatation for stent optimization on clinical outcomes [5–7]. This is noteworthy considering that post-dilatation alone is less expensive and easily implementable in standard daily practice. As a result of the restricted evidence, there is no consensus whether post-dilatation should be used routinely during PCI. Moreover, the extent to which post-dilatation is being utilized remains unclear. The aim of the current study was to determine the frequency of post-dilatation during PCI and to identify the characteristics of individuals in whom post-dilatation is applied, using data of the Netherlands Heart Registration (NHR).

## 2 | Methods

### 2.1 | Data Source

This is an observational, retrospective cohort study of prospectively collected data registered within the NHR. The NHR is an independent organization in which Dutch hospitals prospectively register standard sets of baseline, procedural and outcome data for all invasive cardiac procedures, including PCI [8, 9]. Since Q4 2021, the PCI registry was expanded with an additional variable set regarding procedural characteristics on vessel level. This variable set included number of stents, stent length, maximum stent diameter, strut thickness, use of NC

balloon including its maximum diameter, use of intracoronary imaging (intravascular ultrasound [IVUS] or optical coherence tomography [OCT]) and use of additional preparation techniques (i.e., rotablator or intravascular lithotripsy). Twelve PCI centers collected this additional variable set.

Data provided to the NHR are extensively checked on completeness and quality, reviewed with audit reports by independent trained research nurses and discussed by cardiologists in registration committees [10].

The study was approved by the institutional review board MEC-U (W19.270) and conducted in agreement with the principles of the Declaration of Helsinki. A waiver for informed consent for analysis with the data of the NHR data registry was obtained.

### 2.2 | Study Population

All patients who undergo PCI for any indication are included in the register of the NHR. For the current study we analyzed patients who underwent PCI with stent deployment in the time period from the 4th quarter of 2020 up to the 3rd quarter of 2021. If a patient had multiple PCIs within 365 days, only the first procedure was included. Subsequently, the study population was categorized into two groups: patients that received post-dilatation after stenting (PD-group) and the cohort that did not receive post-dilatation (no PD-group). Post-dilatation was defined as using a NC balloon with a diameter equal to or larger than the diameter of the implanted stent. When no information was available regarding the diameter of stent or NC balloon the patient was excluded. In case of multivessel PCI, a patient was categorized in the PD-group if post-dilatation was performed in at least one of the vessels.

### 2.3 | Primary and Secondary Outcomes

The primary outcome of this study was the rate of post-dilatation use for stent optimization during PCI. Secondary outcomes included the differences in baseline and procedural characteristics of patients that received additional post-dilatation and patients that did not receive post-dilatation. Additionally, post-dilatation rates at center and operator levels were assessed as secondary outcomes.

### 2.4 | Statistical Analyses

Baseline characteristics were described as mean  $\pm$  standard deviations for continuous variables that were normally distributed, median and interquartile range for continuous that were non-normally distributed and percentages for categorical

variables. We used the independent *t*-test for normally distributed continuous data and the Mann–Whitney *U* test for non-normally distributed continuous data. For categorical variables the Pearson's  $\chi^2$  exact test or Fisher's exact test were used as appropriate.

Univariable logistic regression analysis was performed to assess the association between baseline and procedural characteristics and the use of post-dilatation. Subsequently, variables with a  $p < 0.100$  were combined in a multivariable logistic regression model.

Additionally, a Pearson correlation analysis was conducted to assess the relationship between the number of procedures performed by centers and operators and the rate of additional post-dilatation. Only operators who performed  $> 20$  PCIs were included in this analysis.

All tests were two-sided and a  $p$  value of  $<0.050$  was considered statistically significant. The acquired data was analyzed using IBM Statistical Package for Social Sciences (SPSS) for Windows Version 28 (IBM Corporation, Armonk, NY, USA).

## 3 | Results

### 3.1 | Study Population

A total of 12,960 patients were included in this study. Baseline characteristics of the study population are presented in Table 1. The completeness of the provided variables was consistently above 98.0%, except for left ventricular ejection fraction (49.6%). The overall mean age of the patients was 66.8 years ( $\pm 11.3$ ), with 73.1% being male, 22.3% having diabetes, and 29.9% presenting with STEMI.

### 3.2 | Use of Post-Dilatation for Stent Optimization in Contemporary Pci

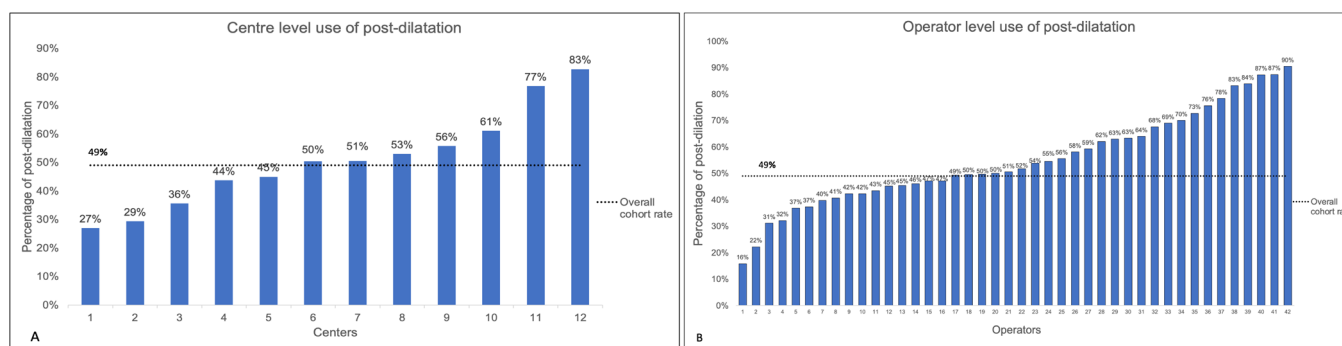
In total, 6338 patients (49.9%) underwent post-dilatation with a NC balloon in one or more vessels. There was a variety in post-dilatation use between centers ranging from 29.3% to 82.9% (Figure 1, panel A). Among operators, the percentage post-dilatation ranged from 15.9% to 90.5% (Figure 1, panel B). Pearson coefficients showed that a higher number of PCIs was moderately

**TABLE 1** | Baseline characteristics.

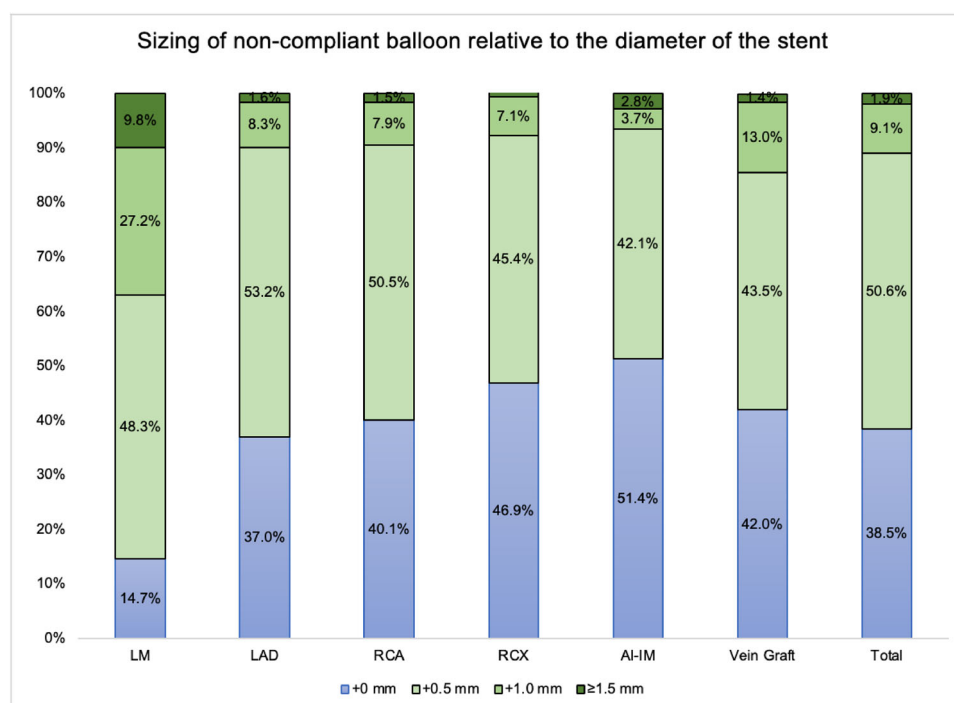
Variables	Total group N = 12,690	No post-dilatation N = 6352	Post-dilatation N = 6338	p value
<i>Patient characteristics</i>				
Age, years (mean $\pm$ SD)	66.8 $\pm$ 11.3	66.9 $\pm$ 11.5	66.7 $\pm$ 11.2	0.32
Gender (male) (No, %)	9279 (73.1)	4612 (72.6)	4667 (73.6)	0.20
Diabetes (No, %)	2829 (22.3)	1423 (22.5)	1406 (22.2)	0.77
Prior MI (No, %)	2839 (22.4)	1386 (21.8)	1453 (23.0)	0.13
Prior PCI (No, %)	3357 (26.5)	1670 (26.3)	1687 (26.6)	0.68
Prior CABG (No, %)	1039 (8.2)	520 (8.2)	519 (8.2)	0.99
<i>Renal function (No, %)</i>				
eGFR <sup>a</sup> $\geq 60$	9667 (76.2)	4795 (76.8)	4872 (78.2)	0.07
eGFR 30–59	2488 (19.6)	1292 (20.7)	1196 (19.2)	0.036
eGFR 15–29	216 (1.)	107 (1.7)	109 (1.7)	0.88
eGFR $< 15$	31 (0.2)	16 (0.3)	15 (0.2)	0.86
Dialysis	75 (0.6)	34 (0.5)	41 (0.6)	0.41
LVEF (median, IQR)	55 [45–55]	55 [45–55]	55 [45–55]	0.53
<i>Indication (No, %)</i>				
Elective	4663 (36.7)	2116 (33.3)	2547 (54.6)	$<0.001$
NSTEMI	4228 (33.3)	2045 (32.2)	2183 (34.4)	0.007
STEMI	3797 (29.9)	2189 (34.5)	1608 (25.4)	$<0.001$
OHCA (No, %)	396 (3.1)	234 (3.7)	162 (2.6)	$<0.001$
Cardiogenic shock (No, %)	402 (3.2)	233 (3.7)	169 (2.7)	0.001
CTO (No, %)	614 (4.8)	291 (4.6)	323 (5.1)	0.18
Multivessel disease (No, %)	6797 (53.6)	3251 (51.2)	3546 (56.0)	$<0.001$

Abbreviations: CABG, indicates coronary artery bypass graft; CTO, chronic total occlusion; eGFR, estimated glomerular filtration rate; MI, myocardial infarction; NSTEMI, non-ST elevation myocardial infarction; OHCA, out of hospital cardiac arrest; PCI, percutaneous coronary intervention; SD, standard deviation; STEMI, ST elevation myocardial infarction.

<sup>a</sup>mL/min/1.73 m<sup>2</sup>.



**FIGURE 1** | This study includes 12,690 patients from 12 PCI centers. Overall post-dilatation was used in 49.9% of the patients. There was a variation in use of post-dilatation among centers ranging from 29.3% to 82.7% (panel A) and among operators ranging from 15.9% to 90.5% (panel B). [Color figure can be viewed at [wileyonlinelibrary.com](http://wileyonlinelibrary.com)]



**FIGURE 2** | Sizing of the non-compliant balloon relative to the stent. The non-compliant balloon most frequently sized 0.5 mm larger than the stent diameter (50.6%). AL-IM, indicates anterolateral/intermediate branch; LAD, left anterior descending; LM, left main; RCA, right coronary artery; RCX, ramus circumflexus. [Color figure can be viewed at [wileyonlinelibrary.com](http://wileyonlinelibrary.com)]

associated with lower use of post-dilatation, both at operator ( $-0.34$ , 95%CI,  $-0.35$  to  $-0.32$ ,  $p < 0.001$ ) and center levels ( $-0.35$ , 95%CI,  $-0.37$  to  $-0.33$ ,  $p < 0.001$ ) (Supporting Information S1: Figure 1).

In case of post-dilatation, the NC balloon was most frequently sized 0.5 mm larger than the stent diameter (50.6%) and matched to the nominal stent diameter in 38.5% of cases (Figure 2). Detailed information regarding NC sizing per coronary artery is displayed in Supporting Information S1: Table 1.

### 3.3 | Clinical Characteristics Associated with Post-Dilatation

Mean age was 66.9 ( $\pm 11.5$ ) in the PD-group and 66.7 ( $\pm 11.2$ ) in the no PD-group ( $p = 0.32$ ), see Table 1. In both groups the majority of patients were male. No differences between the two groups were

observed in the incidence of patients with severely impaired renal function or need of dialysis. In the no PD-group there were significantly more patients presenting with ST-elevation myocardial infarction (STEMI) (34.5% vs. 25.4%,  $p < 0.001$ ), out of hospital cardiac arrest (OHCA) (3.7% vs. 2.6%,  $p < 0.001$ ) and cardiogenic shock (CS) (3.7% vs. 2.7%,  $p = 0.001$ ). In the PD-group there were significantly more patients with multivessel disease (56.0% vs. 51.2%,  $p < 0.001$ ). The indications of OHCA, non-STEMI and STEMI were independently, inversely associated with the use of post-dilatation (Supporting Information S1: Table 2).

### 3.4 | Procedural Characteristics Associated With Post-Dilatation

Overall, 10,371 patients underwent PCI for a single vessel (81.7%) and in 2319 patients (18.3%) PCI was performed in two

**TABLE 2** | Procedural characteristics.

Variables	Total group N = 12,690	No post-dilatation N = 6352	Post-dilatation N = 6338	p value
Vessel (No, %)				
LM	645 (5.1)	179 (2.8)	466 (7.4)	<0.001
LAD	6389 (50.3)	2901 (45.7)	3488 (55.0)	<0.001
AL/IM	316 (2.5)	152 (2.4)	164 (2.6)	0.48
RCX	3096 (24.4)	1612 (25.4)	1484 (23.4)	0.010
RCA	4475 (35.3)	2296 (36.1)	2179 (34.4)	0.037
Vein graft	199 (1.6)	121 (1.9)	78 (1.2)	0.002
Multivessel PCI (No, %)				
1 vessel	10371 (81.7)	5486 (86.4)	4885 (77.1)	<0.001
2 vessels	1749 (13.8)	689 (10.8)	1060 (16.7)	<0.001
3 vessels	397 (3.1)	127 (2.0)	270 (4.3)	<0.001
> 3 vessels	173 (1.4)	50 (0.8)	123 (1.9)	<0.001
Imaging (No, %)				
IVUS	167/8353 (2.0)	30/3861 (0.8)	137/4492 (3.0)	<0.001
OCT	172/8353 (2.1)	40/3861 (1.0)	132/4492 (2.9)	<0.001
Calcium modification therapy (No, %)	229/8353 (2.7)	70/3861 (1.8)	159/4492 (3.5)	<0.001
Stent characteristics				
Stent length, mm (median, IQR)	30.0 [19.0–48.0]	28.0 [18.0–43.0]	33.0 [22.0–48.0]	<0.001
Number of stents (No, %)				
1 stent	7827 (61.7)	4071 (64.1)	3756 (59.3)	<0.001
2 stents	3245 (25.6)	1597 (25.1)	1648 (26.0)	0.27
3 stents	1098 (8.7)	482 (7.6)	615 (9.7)	<0.001
>3 stents	509 (4.0)	201 (3.2)	308 (4.9)	<0.001

Abbreviations: AL-IM, indicates anterolateral/intermediate branch; IQR, interquartile range; IVUS, intravascular ultrasound; LAD, left anterior descending; LM, left main; OCT, optical coherence tomography; PCI, percutaneous coronary intervention; RCA, right coronary artery; RCX, ramus circumflexus.

or more vessels. The left anterior descending artery (LAD) was the most frequently treated coronary artery (50.3%). There were only 12 patients with PCI involving the arterial graft. All procedural characteristics are presented in Table 2.

The proportion of PCI procedures involving the LAD was significantly higher in the PD group (55.0% vs. 45.7%,  $p < 0.001$ ), as were those involving the left main artery (LM) (7.4% vs. 2.8%,  $p < 0.001$ ). Specifically, post-dilatation was performed in 54.6% of cases involving PCI of the LAD and in 72.2% of cases involving PCI of the LM. Use of post-dilatation per coronary artery is shown in Figure 3 panel A.

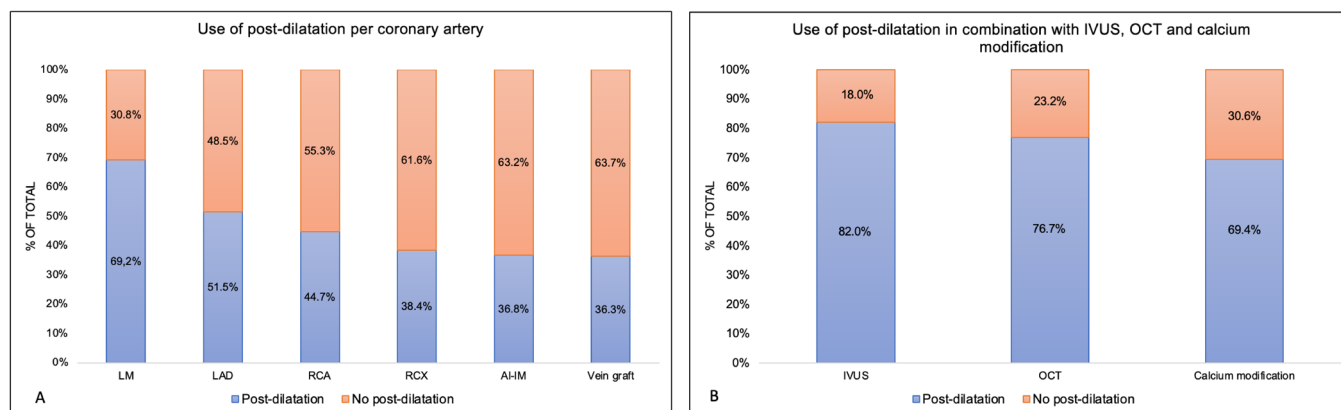
There were significantly more patients with multivessel PCI in the PD-group (22.9%) than in the no PD-group (13.6%),  $p < 0.001$ . Of the patients with multivessel PCI, 784 patients (33.8%) received post-dilatation in all treated vessels. The total stent length was greater in the PD-group as well (median 33.0 mm, IQR [23.0–48.0] vs. 28.0 mm, IQR [18.0–43.0],  $p < 0.001$ ). More information regarding stent characteristics is provided in Supporting Information S1: Table 1.

Data on intracoronary imaging and calcium modification were available for 8353 patients (65.8%). In this group the overall rate of intracoronary imaging or calcium modification was 4.1% and 2.7%, respectively. In case of lesion preparation with calcium modification, post-dilatation was performed in 69.4%. When IVUS or OCT were used, post-dilatation was used in 82.0% and 76.7%, respectively (Figure 3 panel B).

The procedural characteristics that were independently associated with the use of post-dilatation were multivessel PCI, LM PCI, PCI of the LAD the number of stents and total stent length (Supporting Information S1: Table 2). When including intracoronary imaging and calcium modification therapy in the model, these variables remained independently associated with post-dilatation, as well as use of intracoronary imaging and calcium modification (Supporting Information S1: Table 3).

## 4 | Discussion

This study, which is based on real world data from 12 high volume PCI centers, provides a comprehensive overview of the



**FIGURE 3** | Use of post-dilatation per coronary vessel (panel A) and in case of IVUS, OCT and calcium modification therapy (panel B). Overall cohort rate was 49.9%. AL-IM, indicates anterolateral/intermediate branch; IVUS, intravascular ultrasound; LAD, left anterior descending; LM, left main; OCT, optimal coherence tomography; RCA, right coronary artery; RCX, ramus circumflexus. [Color figure can be viewed at [wileyonlinelibrary.com](http://wileyonlinelibrary.com)]

contemporary use of post-dilatation in the Netherlands, highlighting significant variations among centers and operators. The findings indicate that post-dilatation is performed in only half of the patients, with notable differences in patient and procedural characteristics between those who underwent post-dilatation and those who did not.

There was variability in the use of post-dilatation among different centers and operators, accompanied by a moderate negative correlation between the number of procedures performed and the rate of post-dilatation. In current practice, there is no established consensus on when post-dilatation should be performed after stenting, leaving the decision largely to the operator's discretion. Some operators reserve post-dilatation for lesions with known risk factors for restenosis or when a stent is clearly under-expanded, while others adhere a more liberal approach. In the present study, the reasons behind operators' decisions to post-dilate were not documented and detailed lesion characteristics were not present. However, it can be hypothesized that post-dilatation was more frequently performed in lesions with characteristics prone to restenosis, such as calcified lesions, small vessels, bifurcations, long lesions and diffuse CAD [11]. Indicators supporting this assumption include the higher number and greater length of stents used in the PD group, both of which were independently associated with the use of post-dilatation and are known predictors of ISR and ST. Moreover, there were more "complex" PCIs in the PD-group including multivessel PCI and intervention involving the LM. Interestingly, 31% of the patients with LM PCI in our study did not undergo post-dilatation. In LM PCI, discordance between the LM and LAD/circumflex arteries increases the risk of stent undersizing and malapposition, highlighting the importance of proximal optimization technique (POT) to improve outcomes [12]. While some LM PCIs in our study may have been isolated ostial or mid-shaft procedures, the majority presumably involved bifurcations, a considerable part of which were performed without POT. In comparison, the DK CRUSH-V and EBC-Main trials, which investigated PCI in LM bifurcations, reported final POT rates of 99% and

85%, respectively [13, 14]. Lastly, there was a greater use of calcium modification therapy, indicating a higher incidence of severely calcified lesions in this group.

We found that post-dilatation was used less often in STEMI, OHCA and CS patients. One explanation could be that operators may be more reluctant to perform additional procedural steps for stent optimization in patients with unstable clinical presentations. Furthermore, it is thought that post-dilatation in a culprit vessel carries an increased risk of thrombus fragmentation, which could lead to distal embolization and subsequent no-reflow [15, 16]. No-reflow is associated with poorer clinical outcome in STEMI patients [17, 18]. However, some studies have demonstrated that post-dilatation in primary PCI patients can be safely conducted in terms of no additional impairment of the microcirculation while also improving overall stent results [19–21].

At present, there are no recent large randomized controlled trials to provide clarity on the debate if post-dilatation should be used routinely during PCI. Previous studies have suggested a favorable clinical impact of routine use of post-dilatation [22–24]. The potential positive effect of post-dilatation is the inherent ability to correct stent under-expansion and reduce malapposition of the stent struts, both of which are known risk factors for ISR and ST. Angiography is weak in recognizing under-expansion and malapposition leading to an under-estimation of the prevalence of suboptimal stent results. This is reflected by multiple intracoronary imaging studies, which have shown that compared to standard angiography, imaging increases the use of additional procedural steps for stent optimization, including post-dilatation [25, 26]. Similarly, in the present study, imaging led to post-dilatation in 79.4% of patients. Since the majority of the PCIs in this study were not guided by intracoronary imaging (only 4.1%) and did not include post-dilatation, a substantial proportion of patients in this study likely received inadequate stent optimization, potentially resulting in suboptimal stent results. This underscores the opportunity to improve outcomes by incorporating the simple step of post-dilatation during PCI.



The rate of intracoronary imaging was relatively low in this study (4.1%), particularly in comparison to American and Asian registry studies, which reported an imaging rate of 16% and 28%, respectively [27, 28]. The underusage of intracoronary imaging could arise from various factors, including issues specific to level of both operators and hospitals, such as limited experience, hesitancy to dedicate extra time to the procedure, and concerns regarding costs and cost-effectiveness [29]. It is expected that the application of intracoronary imaging will increase, as the clinical importance of imaging guided stent optimization has been emphasized by a recent meta-analysis, compared with angiography guidance [3]. Accordingly, the use of imaging in PCI has been upgraded in the most recent European guidelines to level IA for complex lesions [30].

Despite the strong evidence supporting its value for patients undergoing PCI, it is important to consider that intracoronary imaging increases procedure time and procedural costs. Consequently, imaging is most often used for complex lesions rather than being used routinely for all patients undergoing PCI. A routine and straightforward approach to achieve stent optimization is post-dilatation, which can be easily performed during PCI procedures, with or without imaging [7]. In this context, the OPTIMIZE-PCI project (NCT06558474) has been initiated, in which a liberal post-dilatation strategy is implemented across multiple centers in the Netherlands. Part of the OPTIMIZE-PCI involves educating operators uniformly to adopt post-dilatation as a standard procedure, thereby reducing differences in practices between operators and centers. A final analysis will be conducted to evaluate whether adopting this strategy has led to improved clinical outcomes after PCI in terms of major adverse cardiac events.

#### 4.1 | Limitations

This study has several limitations. First, although most variables were predefined and collected prospectively by the centers, some bias may exist due to the retrospective aspect of this study. Important variables regarding detailed lesion characteristics were not available. However, to vouch for its accuracy, the NHR conducts annual audits for validation and verification, demonstrating a high accuracy of over 95% for nearly all variables [10]. Moreover, the NHR contains real-world data, thus encompassing a broad and unselected patient population.

Second, the procedural data were available on vessel level, not on segment level. For this reason, it cannot be stated with certainty that a stent was post-dilated along its entire length.

Lastly, there is a possibility that certain operators used the same compliant balloon for post-dilatation as they used for the deployment of the stent, which was not classified as post-dilatation according the definition in this study. Bench tests have demonstrated that NC balloons can withstand higher inflation pressures compared to (semi) compliant balloons of the same size. Especially at calcified and fibrotic site of a lesion use of a (semi) compliant balloon can result in inadequate stent expansion. Additionally, such balloons tend to demonstrate a “dog bone” effect at higher pressures which leads to unequal distribution of outward force of the balloon and increases the

risk of edge dissection [31, 32]. Therefore using a NC balloon would be the more judicious option.

## 5 | Conclusion

Stent optimization with post-dilatation using NC balloon is performed in only half of the patients undergoing PCI in the Netherlands, with variations in frequency across centers and operators. Post-dilatation is more often used in cases of complex PCI and when intracoronary imaging or calcium modification techniques are used. Future studies are needed to better define the role of routine post-dilatation in improving clinical outcomes during PCI.

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### Conflicts of Interest

The authors declare no conflicts of interest.

### Data Availability Statement

The data underlying this article were provided by the Netherlands Heart Registration (NHR) by permission.

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## Supporting Information

Additional supporting information can be found online in the Supporting Information section.