Cardiovascular Revascularization Medicine 20 (2019) 289–292

Contents lists available at ScienceDirect

Cardiovascular Revascularization Medicine

Clinical

Prevalence, Trends, and Outcomes of Higher-Risk Percutaneous Coronary Interventions Among Patients Without Acute Coronary Syndromes☆,☆☆

Ann Iverson [a], Larissa I. Stanberry [a], Peter Tajti [a], Ross Garberich [a], Amber Antos [a], M. Nicholas Burke [a], Ivan Chavez [a], Mario Gössl [a], Timothy D. Henry [a,b], Daniel Lips [a], Michael Mooney [a], Anil Poulose [a], Paul Sorajja [a], Jay Traverse [a], Yale Wang [a], Steven Bradley [a], Emmanouil S. Brilakis [a,*]

[a] Minneapolis Heart Institute Foundation at Abbott Northwestern Hospital, 920 East 28th Street, Suite 100, Minneapolis, MN 55407, USA
[b] Cedars Sinai Medical Center, 8700 Beverly Blvd, Los Angeles, CA 90048, USA

ARTICLE INFO

Article history:
Received 15 April 2018
Received in revised form 17 July 2018
Accepted 18 July 2018

Keywords:
Bifurcation lesions
Chronic total occlusions (CTO)
Multivessel PCI

ABSTRACT

Background/purpose: Patients and lesions at a higher procedural risk for percutaneous coronary intervention (PCI) are an understudied population. We examined the frequency, clinical characteristics, and outcomes of higher risk and non-higher risk PCIs at a large tertiary center.
Methods/materials: The following procedures were considered higher risk: unprotected left main PCI, chronic total occlusion PCI, PCI requiring atherectomy, multivessel PCI, bifurcation PCI, PCI in prior coronary artery bypass graft surgery (CABG) patients, pre-PCI left ventricular ejection fraction ≤30%, or use of hemodynamic support.
Results: Of the 1975 PCIs performed from 6/29/09 to 12/30/2016 in patients without acute coronary syndromes, 1230 (62%) were higher risk. Patients undergoing higher risk PCI were more likely to have a history of CABG, myocardial infarction, PCI, cerebrovascular disease, peripheral arterial disease, or congestive heart failure. Higher risk PCIs required more stents (2.0 vs. 1.0, $p < 0.001$), and had longer median fluoroscopy times (17.3 vs. 8.5 min, $p < 0.001$) and higher median contrast doses (160 vs. 120 mL, $p < 0.001$). In higher risk PCIs, the risks for technical failure and periprocedural complications were 2.9 (95% CI 1.2–7.4) times and 2.2 (95% CI 0.9–5.4) times higher as compared with non-higher risk PCI procedures.
Conclusions: In summary, over half of the PCIs performed in non-acute coronary syndrome patients were higher risk and were associated with lower odds of technical success and higher periprocedural complication rates as compared with non-higher risk PCIs.
Summary: We examined the frequency, clinical characteristics, and outcomes of higher risk and non-higher risk PCIs at a large tertiary center. Higher risk PCI was associated with lower odds of technical and procedural success and higher odds of procedural complications as compared with non-higher risk PCI. However, the risk/benefit ratio may still be favorable for many of these higher-risk patients and should be estimated on a case by case basis.

1. Introduction

In recent years, there has been increased interest in the use of percutaneous coronary intervention (PCI) to treat coronary artery disease in complex lesions and higher risk patients, such as those with comorbidities and poor hemodynamic status [1,2]. While many of these higher risk patients could potentially benefit from PCI, they are often undertreated, due to concerns for low success rates and increased risk for complications [3]. We reviewed consecutive cases from a large, tertiary care center to examine the prevalence and characteristics of higher risk PCIs and determine factors associated with technical and procedural success.

2. Material and methods

We performed a retrospective study of patients who underwent PCI between June 29, 2009 and December 30, 2016 at Abbott Northwestern Hospital, Minneapolis, Minnesota. Patients presenting with ST-elevation myocardial infarction (STEMIs), non-ST-elevation myocardial infarction (NSTEMIs), or unstable angina were excluded, as were patients in

☆ **Disclosures:** One or more of the authors have disclosed potential conflicts of interest regarding the content herein. Dr. Burke reports consulting and speaking honoraria from Abbott Vascular and Boston Scientific. Dr. Brilakis reports consulting/speaker honoraria from Abbott Vascular, ACIST, Amgen, Asahi, CSI, Elsevier, GE Healthcare, Medicure, Medtronic, and Nitiloop and research support from Boston Scientific and Osprey. He serves in the Board of Directors of the Cardiovascular Innovations Foundation and the Board of Trustees of the Society of Cardiovascular Angiography and Interventions. Dr. Traverse reports an NIH grant. The remaining authors have no disclosures to report.
☆☆ **Funding:** This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

* Corresponding author at: 800 East 28th Street, Suite 300 – MR 33300, Minneapolis, MN 55407, USA.
E-mail address: esbrilakis@gmail.com (E.S. Brilakis).

https://doi.org/10.1016/j.carrev.2018.07.017
1553-8389/

cardiogenic shock at the time of PCI. Data collection was performed retrospectively from the National Cardiovascular Data Registry (NCDR) CathPCI Registry. The study was approved by the Allina Health Institutional Review Board.

Higher risk PCIs were defined as those meeting any of the following criteria: unprotected left main coronary artery lesion, chronic total occlusion, procedure requiring atherectomy, multivessel PCI, bifurcation PCI, patient with prior coronary artery bypass graft (CABG) surgery, pre-PCI left ventricular ejection fraction ≤30%, or use of intra-aortic balloon pump or other hemodynamic support.

The primary endpoints in this study were technical and procedural success and major procedural complications. Technical success was defined as successful revascularization with achievement of ≤30% diameter stenosis within the treated segment and restoration of TIMI grade 3 flow in at least one lesion treated during the procedure. Procedural success was defined as technical success without any major procedural complications. Major procedural complications included any of the following adverse events prior to hospital discharge: death, myocardial infarction (MI), complication requiring emergency coronary artery bypass graft surgery (CABG), tamponade, and stroke.

Categorical variables were summarized as counts (percentages) and compared using Pearson's chi-squared test, or Fisher's exact test for small counts. Continuous variables were summarized by their means ± standard deviations (medians) and compared using the *t*-test and Wilcoxon rank sum for normally distributed and skewed variables, respectively. Two-sided p-values of 0.05 were considered statistically significant. The relative risks for technical failure and periprocedural complications in higher risk PCIs as compared with non-higher risk PCIs were estimated using a multivariatelog-binomial model to adjust for age, gender, prior cardiac events (history of MI, PCI, CABG, cerebrovascular disease, congestive heart failure, peripheral arterial disease), median preprocedural TIMI flow, and the number of lesions treated during the procedure. Records with missing data were excluded from the regression analysis. The results of the multivariate analyses are reported as estimated relative risks with the corresponding 95% confidence intervals. The annual change in PCI volumes was estimated using a univariate linear regression. The annual trends in PCI volumes for different risk groups were estimated using Poisson regression with an interaction term for a risk group and a log-offset for the total annual volumes; results are reported as the estimated annual percent changes and the corresponding 95% confidence intervals. All statistical analyses were performed with R 3.4.0 (R Foundation for Statistical Computing; Vienna, Austria) in RStudio (RStudio Team; Boston, Massachusetts).

3. Results

Of the 1979 non-ACS PCIs performed at our institution from 6/29/09 to 12/30/2016, 1230 (62%) were higher risk. The annual PCI volume remained constant over time; with the estimated annual change of 0.01% (95%CI −1.8, 1.9, p = 0.61). The annual volume of the higher-risk procedures appeared to decrease by 3.2% (95% CI 0.9, 5.5, p = 0.01) over the study period (Fig. 1).

As compared with patients undergoing non-higher risk PCIs, patients undergoing higher risk PCIs were more likely to be men and to have diabetes mellitus, cerebrovascular disease, peripheral arterial disease, congestive heart failure, prior PCI, CABG, or MI, and a lower ejection fraction (Table 1).

Higher risk PCI had longer lesions and lower baseline TIMI flow and were less likely to involve restenotic lesions (Table 2). Enoxaparin and glycoprotein IIb/IIIa inhibitors were administered more often in higher risk PCIs. Nearly a third of higher risk PCIs underwent treatment of at least one bifurcation lesion and 18% of patients underwent PCI of at least one CTO lesion. Higher risk PCIs had more stents implanted during the procedure, longer median fluoroscopy times, and greater contrast dose per lesion as compared with non-higher risk PCIs (Table 3).

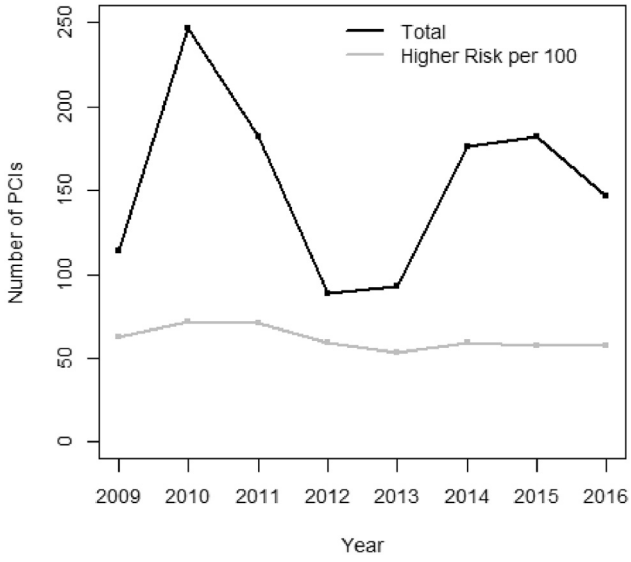

Fig. 1. Annual volumes of PCIs (black) and the yearly number of higher risk PCIs per 100 interventions (gray) Abbreviations: PCI = percutaneous coronary intervention.

The cumulative incidence of both technical failure and procedural complications was higher in higher risk PCIs than non-higher risk PCIs: 5% vs 2% (p < 0.001) and 3% vs 1% (p = 0.01), respectively (Fig. 2). In the adjusted model, higher risk PCI patients had 2.92 (95%CI 1.16, 7.36) times the risk of technical failure during the procedure and 2.21 (95%CI 0.91, 5.35) times the risk of periprocedural complications as compared with non-higher risk PCI patients.

Out of 35 higher risk PCIs with periprocedural complications, 8 (23%) required blood transfusion and 3 (9%) had vascular complications. From 1230 higher-risk PCI patients, those who experienced complications during the procedure were older (73 ± 12 vs 67 ± 11 years;

Table 1
Baseline characteristics of patients undergoing percutaneous coronary artery intervention, stratified according to procedural risk.

Variable[a]	Higher risk PCI n = 1230	Nonhigher risk PCI n = 745	p value
Age, y	67 ± 11 (68)	68 ± 11 (68)	0.310
Male	977 (79)	530 (71)	<0.001
Caucasian	1169 (95)	715 (96)	0.910
Hypertension	1004 (82)	589 (79)	0.180
Dyslipidemia	1143 (93)	685 (92)	0.474
Prior CABG surgery	336 (27)	0 (0)	<0.001
Diabetes mellitus	425 (35)	247 (33)	0.557
Non-insulin dependent	272 (22)	165 (22)	1.0
Insulin-dependent	153 (12)	82 (11)	0.378
Smoking	188 (15)	111 (15)	0.868
Prior MI	432 (35)	194 (26)	<0.001
Prior PCI	495 (40)	257 (34)	0.012
Cerebrovascular disease	203 (17)	90 (12)	0.009
Peripheral Arterial Disease	211 (17)	93 (12)	0.006
Currently on dialysis	30 (2)	15 (2)	0.641
Chronic Lung Disease	171 (14)	118 (16)	0.265
Body Mass Index, kg/m^2	32 ± 7 (31)	31 ± 7 (30)	0.067
Pre-PCI LVEF, %	51 ± 15 (55)	58 ± 10 (60)	<0.001
Pre-PCI LVEF<50%	624(27)	132(15)	<0.001
Symptoms			0.173
No angina	399 (32)	272 (37)	
Stable angina	616 (50)	354 (48)	
Atypical chest pain	215 (17)	119 (16)	
Congestive Heart Failure	319 (26)	131 (18)	<0.001

Abbreviations: ACS = acute coronary syndrome; CABG = coronary artery bypass graft surgery; MI = myocardial infarction; PCI = percutaneous coronary intervention. LVEF = Left ventricular ejection fraction.

[a] Data summaries: counts (%) for categorical and mean ± standard deviation (median) for continuous variables.

Table 2
Lesion characteristics of patients undergoing percutaneous coronary artery intervention, classified according to procedural risk.

Variable[a]	Higher risk PCI n = 2282	Nonhigher risk PCI n = 896	p value
Restenotic lesion	125 (5)	67 (7)	0.041
CTO lesion	246(11)	0(0)	<0.001
Bifurcation lesion	518(23)	0(0)	<0.001
Lesion length, mm	19 ± 14 (15)	18 ± 11 (15)	0.035
Use of atherectomy	67(3)	0(0)	<0.001
Pre-procedure TIMI flow			<0.001
3	1658 (73)	781 (87)	
2	256 (11)	78 (9)	
1	80 (4)	35 (4)	
0	265 (12)	0 (0)	
Post-procedure TIMI flow			0.017
3	2170 (95)	881 (98)	
2	13 (1)	0 (0)	
1	3 (<1)	2 (<1)	
0	24 (1)	4 (<1)	

Abbreviations: TIMI = Thrombolysis in Myocardial Infarction.
[a] Data summaries: counts (%) for categorical and mean ± standard deviation (median) for continuous variables.

p < 0.001), had longer lesions (24 ± 16 vs 19 ± 14, p = 0.002), and had higher incidence of one or more unprotected LMCA lesions (6/35 = 17% vs 53/1195 = 4%) than patients who had no periprocedural complications. The higher risk PCIs with complications had longer fluoroscopy time 33 ± 14 (24) vs 23 ± 18 (17) min (p = 0.01), higher contrast volumes 213 ± 84 vs 174 ± 81 mL (p = 0.01), and more frequent use of intraaortic balloon pump 3/35 = 9% vs 9/1195 = 1%

Table 3
Summary of treatments, procedural variables, and outcomes in CathPCI Registry patients undergoing percutaneous coronary artery intervention classified according to procedural risk.

Variable[a]	Higher risk PCI n = 1230	Nonhigher Risk PCI n = 745	p value
Unfractionated heparin	987 (80)	581 (78)	0.467
Enoxaparin	13 (1)	1 (<1)	0.022
Bivalirudin	334 (27)	194 (26)	0.629
Glycoprotein IIb/IIIa inhibitor	40 (3)	11 (1)	0.018
No. unprotected LMCA lesions >0	59 (5)	0 (0)	<0.001
No. CTO lesions >0	222 (18)	0 (0)	<0.001
No. Bifurcation lesions >0	395 (32)	0 (0)	<0.001
Arterial Access Site			<0.001
Femoral	1159 (94)	672 (90)	
Radial	61 (5)	72 (10)	
Multivessel PCI	708 (58)	129 (17)	<0.001
No. of stents implanted	1.7 ± 1.0 (2.0)	1.1 ± 0.5 (1.0)	<0.001
No. of drug eluting stents[b]	1.5 ± 1.0 (1.0)	1.0 ± 0.6 (1.0)	<0.001
No. Drug eluting stents			<0.001
One	458 (37)	539 (72)	
Two or more	576 (47)	85 (11)	
Use of intra-aortic balloon pump	24 (1)	0 (0)	<0.001
Fluoroscopy time (min)	23.0 ± 18.7 (17.3)	11.8 ± 9.9 (8.5)	<0.001
Contrast use, mL	176.5 ± 80.8 (160.0)	124.3 ± 49.6 (120.0)	<0.001
Outcomes			
Transfusion	24 (2)	11 (1)	0.486
Vascular complications	10 (1)	4 (1)	0.587
Technical success	1163 (95)	733 (98)	<0.001
Procedural Success	1135 (92)	728 (98)	<0.001
Procedural complications[c]	35 (3)	8 (1)	0.010
In-hospital mortality	12 (1)	1 (<1)	0.040
In-lab mortality	2 (<1)	0 (0)	–

Abbreviations: PCI = percutaneous coronary intervention, LMCA = left main coronary artery.
[a] Data summaries: counts (%) for categorical and mean ± standard deviation (median) for continuous variables.
[b] In patients receiving at least one drug eluting stent.
[c] In-lab or in-hospital death, periprocedural myocardial infarction, stroke, emergent coronary artery bypass graft surgery, tamponade.

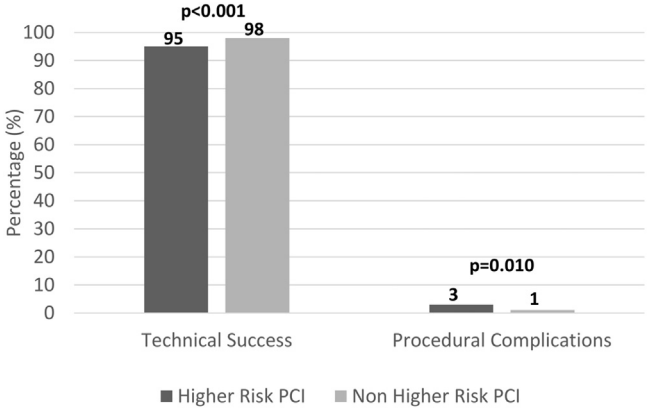

Fig. 2. Procedural outcomes and complications or patients undergoing percutaneous coronary artery intervention, classified according to procedural risk. Abbreviations: PCI = percutaneous coronary intervention.

than higher-risk PCIs with no periprocedural complications. Overall, 28/30 (80%) PCIs were deemed technically successful. For more details, see Supplementary Tables S1–S3 in the appendix.

4. Discussion

In this single-center study, we found that technical success was lower and the risk of complications higher for higher-risk as compared with non-higher risk PCIs. However, the absolute success rate of higher-risk PCIs was high (95%) and the absolute complication rates relatively low (3%), suggesting that the risk/benefit ratio is likely to be favorable for many of these higher-risk procedures.

Recently, there has been increasing interest in offering PCI to higher risk patients who may not have been offered revascularization in the past [3]. There are several potential reasons why these patients might not be offered PCI. Some hospitals might be concerned that treating higher risk patients may adversely affect their risk adjusted mortality scores, although there is evidence to suggest this is not the case [4]. Hospitals may also be concerned that treating higher risk patients might increase their 30 day readmission rates [5]. It is also likely that a significant portion of higher risk patients who may benefit from PCI do not come to the attention of interventional cardiologists [3]. The main concern, however, appears to be that these patients have a low likelihood for procedural success relative to their risk [3].

The increased risk of technical failure and major procedural complications in higher risk PCIs as compared with non-higher risk procedures might explain physicians' reluctance to treat certain higher risk patients. Still, given the high technical success rate (95%), it is possible that the moderately increased risk of adverse events may be acceptable to some patients given the potential benefits of the procedure. It is also possible that success can be improved by appropriate patient selection. CTO PCI has lower success rates than non CTO PCI, but experienced operators can achieve high ≥85% success rates [6–10]. It is likely that patients undergoing any type of higher risk PCI would benefit from having the procedure performed by experienced operators at high-volume tertiary centers [11].

Our study has limitations. First, the center at which the study was performed has experienced, high-volume operators, which may have contributed to low numbers of procedural complications and technical failures resulting in an underestimation of the risk experienced by patients whose procedures are performed by less experienced operators. Second, we did not stratify patients according to their individual risk factors, meaning that different individuals within the higher risk group could have drastically different levels of individual risk. Further research into individual risk factors could help define the level of risk for individual patients.

Even though higher risk PCI was associated with higher risk of technical failure and procedural complications as compared with non-higher risk PCI, the risk/benefit ratio may be favorable for higher-risk patients. Additional data on procedural long-term outcomes and hospitalization costs are required to conduct a comprehensive risk-benefit analysis.

Acknowledgement

The authors would like to thank the Minneapolis Heart Institute Foundation intern program funders, including the Abbott Northwestern Hospital Foundation, Ruth Stricker Dayton, Richard D. Kantrud, the Culp Family Foundation, Piper Jaffray, and many individual contributors for their ongoing support.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.carrev.2018.07.017.

References

[1] Brennan JM, Curtis JP, Dai D, Fitzgerald S, Khandelwal AK, Spertus JA, et al. Enhanced mortality risk prediction with a focus on high-risk percutaneous coronary intervention: results from 1,208,137 procedures in the NCDR (National Cardiovascular Data Registry). JACC Cardiovasc Interv 2013;6:790–9.

[2] Endo A, Kawamura A, Miyata H, Noma S, Suzuki M, Koyama T, et al. Angiographic lesion complexity score and in-hospital outcomes after percutaneous coronary intervention. PLoS One 2015;10:e0127217.

[3] Kirtane AJ, Doshi D, Leon MB, Lasala JM, Ohman EM, O'Neill WW, et al. Treatment of higher-risk patients with an indication for revascularization: evolution within the field of contemporary percutaneous coronary intervention. Circulation 2016;134:422–31.

[4] Sherwood MW, Brennan JM, Ho KK, Masoudi FA, Messenger JC, Weaver WD, et al. The impact of extreme-risk cases on hospitals' risk-adjusted percutaneous coronary intervention mortality ratings. JACC Cardiovasc Interv 2015;8:10–6.

[5] Wasfy JH, Rosenfield K, Zelevinsky K, Sakhuja R, Lovett A, Spertus JA, et al. A prediction model to identify patients at high risk for 30-day readmission after percutaneous coronary intervention. Circ Cardiovasc Qual Outcomes 2013;6:429–35.

[6] Brilakis ES, Banerjee S, Karmpaliotis D, Lombardi WL, Tsai TT, Shunk KA, et al. Procedural outcomes of chronic total occlusion percutaneous coronary intervention: a report from the NCDR (National Cardiovascular Data Registry). JACC Cardiovasc Interv 2015;8:245–53.

[7] Harding SA, Wu EB, Lo S, Lim ST, Ge L, Chen JY, et al. A new algorithm for crossing chronic total occlusions from the asia pacific chronic total occlusion club. JACC Cardiovasc Interv 2017;10:2135–43.

[8] Maeremans J, Walsh S, Knaapen P, Spratt JC, Avran A, Hanratty CG, et al. The hybrid algorithm for treating chronic total occlusions in Europe: the RECHARGE registry. J Am Coll Cardiol 2016;68:1958–70.

[9] Sapontis J, Salisbury AC, Yeh RW, Cohen DJ, Hirai T, Lombardi W, et al. Early procedural and health status outcomes after chronic total occlusion angioplasty: a report from the OPEN-CTO registry (outcomes, patient health status, and efficiency in chronic total occlusion hybrid procedures). JACC Cardiovasc Interv 2017;10:1523–34.

[10] Habara M, Tsuchikane E, Muramatsu T, Kashima Y, Okamura A, Mutoh M, et al. Comparison of percutaneous coronary intervention for chronic total occlusion outcome according to operator experience from the Japanese retrograde summit registry. Catheter Cardiovasc Interv 2016;87:1027–35.

[11] Brilakis ES. Manual of Coronary Chronic Total Occlusion Interventions. A Step-By-Step Approach. 2nd edition. Elsevier; 2017.