



Outcomes of New-Generation Drug-Eluting Stents in Women with Acute Myocardial Infarction

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Abstract

Purpose of Review This review discusses the outcomes of percutaneous coronary intervention (PCI) in women who experience acute myocardial infarction (AMI) and are treated with drug-eluting stents (DES). The review also describes the role of the new-generation DES compared with the early generation.

Recent Findings Recent literature shows that the new-generation DES can be effective in women who present with AMI.

Summary Women with AMI may be undertreated and are underrepresented in studies of AMI. Recently, it has been shown that the newer generation DES are effective and beneficial in women with AMI, similar to men. As further generations of DES are created, the future appears promising for continued advancements in women's cardiovascular health.

Keywords Drug-eluting stent · Women · Females · Acute coronary syndrome · Percutaneous coronary intervention · Myocardial infarction

Introduction

Most studies of AMI have predominately involved men so a dearth of data exists in women with AMI. For example, the Harmonizing Outcomes with Revascularization and Stents in Acute Myocardial Infarction (HORIZONS-AMI) trial [1] evaluated 3602 patients, of which only 23.4% were women. The patients underwent PCI with DES or bare metal stent (BMS) for ST elevation myocardial infarction (STEMI) using heparin and glycoprotein IIb/IIIa inhibitors or bivalirudin. The study found that women had significantly increased 3-year major adverse cardiac events (MACE) and major bleeding. Female sex was an independent predictor of major bleeding (hazard ratio (HR) of 1.81, 95% confidence interval (CI) 1.41–2.33, $p < 0.0001$). A meta-analysis [2] evaluated the sex differences in short- and long-term outcomes of PCI for STEMI and found an increased mortality amongst women. Furthermore, women with acute coronary syndrome (ACS)

are generally older with increased comorbidities such as hypertension, heart failure, and diabetes, although they may have a lower incidence of prior myocardial infarction (MI) and obstructive coronary artery disease (CAD) [3]. Subsequently, recent studies have evaluated the treatment of AMI in women using new-generation DES [4, 5, 6]. This review discusses the gender disparities in AMI treatment, the comparison of outcomes in women vs. men with AMI, and the effects of the new-generation DES in women.

Registry and Retrospective Studies of Women and Men Undergoing PCI

In the New York State PCI reporting system [7], the outcomes of 2561 women (18.1%) and 11,652 men (≤ 50 years old) who were undergoing their first PCI were analyzed between 1999 and 2002. Women had greater rates of in-hospital mortality (0.70% vs. 0.22%, $p < 0.0001$) and vascular injury (0.82% vs. 0.24%, $p < 0.0001$) compared with men. In multivariate analysis, female gender independently predicted in-hospital mortality (odds ratio (OR) 4.0, 95% CI 1.9–8.1) after adjustment for urgency of PCI, clinical, and procedural characteristics. Women were found to have more comorbidities compared with men, which may explain the increased female in-hospital mortality.

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Data from the CathPCI registry (National Cardiovascular Data Registry-NCDR) between 2005 and 2008 (1,079,751 patient PCI admissions) was used to evaluate the age-based (young <55 and older \geq 55 years) and sex-based (men ($n = 720,179$; 66.7%) and women ($n = 359,572$; 33.3%)) differences and in-hospital PCI complication rates and mortality [8]. In risk-adjusted analyses, younger ($n = 61,493$; OR 1.24, 95% CI 1.16–1.33) and older women ($n = 298,079$; OR 1.27, 95% CI 1.09–1.47) were more likely to experience any complication compared with similarly aged men. Any bleeding complication was also higher in women (young, OR 2.12; 95% CI 1.94–2.32 and older, OR 1.76; 95% CI 1.68–1.84). Younger women who underwent elective PCI had twice the mortality risk compared with men (OR 2.04, 95% CI 1.15–3.61). Hence, radial approach may be especially beneficial in women to mitigate bleeding complications.

The PROMETHEUS study [9] was a retrospective multicenter US ACS study of women vs. men (age <55 years) treated with PCI. In 4851 patients (women = 1162; 24.0%) with 1-year follow-up, women had more diabetes (41.0% vs. 27.9%, $p < 0.001$), prior stroke (8.1% vs. 4.2%, $p < 0.001$), prior peripheral arterial disease (9.1% vs. 5.0%, $p < 0.001$), hypertension (74.0% vs. 70.0%, $p = 0.009$), and chronic kidney disease (12.7 vs. 7.2%, $p < 0.001$). Prasugrel was used less often in women ($p = 0.01$). Bivalirudin and glycoprotein IIb/IIIa inhibitor use was significantly lower in women (28.0% vs. 31.7%, $p = 0.016$ and 25.5% vs. 31.3%, $p < 0.001$). Therefore, women had increased comorbidities and underutilization of antiplatelets and anticoagulants. However, adjusted risk analyses showed no difference in 1-year MACE or bleeding.

A study of 109,708 patients who underwent PCI (33% women, January 1994 to January 1998) utilizing data from the National Cardiovascular Network showed that women were older and smaller and had increased comorbidities compared with men, albeit, less severe CAD [10]. In risk-adjusted analyses, women and men had no significant differences in mortality (adjusted OR 1.07, 95% CI 0.92–1.24). However, women had an increased risk of stroke (0.4% vs. 0.2%, OR 1.36, 95% CI 1.1–1.7, $p = 0.001$), vascular complications (5.4% vs. 2.7%, OR 1.48, 95% CI 1.3–1.7, $p = 0.001$), and repeat in-hospital revascularization (4.8% vs. 4.4%, OR 1.13, 95% CI 1.1–1.2, $p = 0.005$).

In the British Cardiovascular Intervention Society (BCIS) and the Swedish Coronary Angiography and Angioplasty Registry (SCAAR) [11], 458,261 patients (BCIS: $n = 368,492$; 25.9% women; SCAAR: $n = 89,769$; 27.2% women) who had PCI for stable angina, STEMI, and non-ST elevation myocardial infarction (NSTEMI) from 2007 to 2011 were evaluated for gender differences and predictors of all-cause mortality at 30 days and 1 year. In the BCIS registry, female sex was an independent predictor of all-cause mortality (30 days OR 1.15, 95% CI 1.10–1.22, $p < 0.0001$) and (1 year

OR 1.08, 95% CI 1.04–1.12, $p < 0.0001$). In the SCAAR registry, female sex was also an independent predictor of all-cause mortality (30 days OR 1.15, 95% CI 1.05–1.26, $p = 0.002$) and (1 year OR 1.09, 95% CI 1.03–1.17, $p = 0.006$). In both registries, women were older ($p < 0.0001$) with more hypertension, diabetes, hypercholesterolemia, NSTEMI, and cardiogenic shock ($p < 0.0001$). Moreover, women required more blood transfusions and developed renal failure/dialysis, tamponade, and coronary perforation ($p < 0.0001$).

Thus, women may have increased comorbidities due to inadequate medical treatment or undiagnosed disease. Also, smaller vessels and hormonal influences may contribute to disparity in complications. Further randomized controlled trials in AMI comparing women vs. men are necessary for definitive conclusions.

Clinical Studies of ACS Treatment in Women and Men

In a population-based cohort study from 2008 to 2011 in Ontario, Canada, by Udell et al. [12], 23,473 ACS patients (8092 women, 34.5%) underwent PCI or no PCI and were followed for 2 years. In propensity-weighted cohort of PCI patients, 1-year rate of death or recurrent ACS was 10.6% (men) and 13.1% (women) with HR 1.24 (95% CI 1.16–1.33) and 2-year rate was 14.8% (men) and 17.4% (women) with HR 1.20 (95% CI 1.13–1.27). Of the patients who did not undergo PCI, outcomes between gender (women, 17.8%; men, 16.9%) did not differ at 1-year or longer follow-up (HR 1.06, 95% CI 0.99–1.14). Compared with men, women were found to be older with more comorbidities.

In a study using the National Inpatient Sample (NIS) database from 2004 to 2011, the temporal trends and sex differences in revascularization and outcomes of STEMI patients (18–59 years) were studied [13]. Of 1,363,492 AMI patients, 632,930 (46.4%) had STEMI. Young women compared with men who had STEMI were less likely to receive PCI (adjusted OR 0.74; 95% CI 0.73–0.75, $p < 0.001$), coronary artery bypass grafting (adjusted OR 0.61; 95% CI 0.60–0.62, $p < 0.001$), or thrombolysis (adjusted OR 0.80; 95% CI 0.78–0.82, $p < 0.001$). Younger women also had increased in-hospital mortality (4.5% vs. 3.0%, adjusted OR 1.11; 95% CI 1.07–1.15, $p < 0.001$). Irrespective of the type of revascularization, women had 11% greater in-hospital mortality ($p < 0.001$). Therefore, the apparent differences in treatment of women with AMI may have led to worse outcomes in women. Similarly, in data from 104,817 ACS patients (women = 41,264; 39.4%) from the American Heart Association Get With The Guidelines Coronary Artery Disease Registry, women with STEMI (<55 years) had increased in-hospital mortality compared with men (OR 1.49, 95% CI 1.12–1.98, $p = 0.006$) and door-to-balloon time of ≤ 90 min was lower (OR 0.80, 95% CI 0.69–0.93, $p = 0.003$) [3•]. In NSTEMI, results were comparable with an increased in-hospital mortality (OR

Table 1 Clinical studies of women vs. men with ACS undergoing PCI

Study (type)	Patients (n)	Outcomes (follow-up)	Results
Udell et al. [12] (population-based cohort—ACS patients; Ontario, Canada)	23,473 ACS; 51.8% women PCI; 66.1% men PCI	All-cause mortality, recurrent hospitalization (2 years)	PCI women = higher mortality and recurrent ACS (2-year rate women 17.4%, men 14.8%; HR 1.20 (95% CI 1.13–1.27))
National Inpatient Sample [13] (registry, 2004–2011)	1,363,492 AMI; 632,930 STEMI; 142,075 women (22.4%)	Trends, sex differences in outcomes young STEMI patients (< 60 years)	Young women = greater in-hospital mortality (4.5% vs. 3.0%, adjusted OR 1.11; 95% CI 1.07–1.15, $p < 0.001$)
Get with the Guidelines Coronary Artery Disease [3•] (registry, 2003–2008)	104,817 ACS; women 41,264 (39.4%)	Sex differences in ACS outcomes	Young women (< 55 years) STEMI = increased in-hospital mortality (OR 1.49, 95% CI 1.12–1.98, $p = 0.006$); door-to-balloon time ≤ 90 min = lower (OR 0.80, 95% CI 0.69–0.93, $p = 0.003$). Young women NSTEMI = increased in-hospital mortality (OR 1.47, 95% CI 1.22–1.77, $p < 0.0001$)

ACS, acute coronary syndrome; PCI, percutaneous coronary intervention; HR, hazard ratio; CI, confidence interval; AMI, acute myocardial infarction; STEMI, ST elevation myocardial infarction; OR, odds ratio; NSTEMI, non-ST elevation myocardial infarction

1.47, 95% CI 1.22–1.77, $p < 0.0001$) for women vs. men (< 55 years). Clinical studies of women and men with ACS are listed in Table 1.

In a single-center retrospective study of 4776 patients, women (24.2%) and men with ACS treated with contemporary PCI techniques were evaluated for mortality and MACE [14]. No significant difference was noted in unadjusted 1-year MACE between women and men (11.6% vs. 10.8%, $p = 0.434$) or mortality. Therefore, conflicting data exists in the outcomes of PCI in women compared with men. Based on the registry and cohort studies, women have increased mortality in AMI with delayed treatment and less successful door-to-balloon times of ≤ 90 min. This suggests that focus on improving outcomes of women with AMI may be beneficial.

Data from Randomized Controlled Trials in Women

In the HORIZONS-AMI trial [1], the symptom-onset-to-balloon time was significantly greater in women (237.5 vs. 218 min, $p = 0.007$). This was attributed to later presentation to the hospital after symptom onset in women. Also, symptom-onset-to-door time was significantly greater in women (120 vs. 110 min, $p = 0.01$).

In the Women in Innovation Initiative-Drug-Eluting Stent (WIN-DES) Collaborative Patient-Level Pooled Analysis [4•], 26 randomized controlled trials of early-generation DES (sirolimus- and paclitaxel-eluting stents) vs. new-generation DES (everolimus- and zotarolimus-eluting stents with durable polymer and biolimus- and sirolimus-eluting stents with biodegradable polymer) in women who suffered AMI (NSTEMI and STEMI) were evaluated for long-term safety and efficacy (3-year follow-up). Of 11,577 women, 2176 (18.8%) had an AMI. New-generation DES had lower death, myocardial infarction (MI), or target lesion revascularization compared with early-generation DES (14.9% vs. 18.4%; adjusted hazard ratio, 0.78; 95% CI, 0.61–0.99). New-generation DES also had lower definite or probable stent thrombosis (1.4% vs. 4.0%; adjusted hazard ratio, 0.36; 95% CI, 0.19–0.69). The study determined that the new-generation DES in women was associated with durable benefits over 3 years. Moreover, procedural complexity did not affect the thrombotic safety profile of the new-generation DES. Furthermore, another study of pooled patient-level data from 26 randomized controlled trials in women showed that STEMI was independently associated with increased 3-year mortality (HR 3.45, 95% CI 1.99–5.98, $p < 0.01$) [15]. No difference was noted in NSTEMI, unstable angina, or stable angina. In women who presented with ACS, the new-generation DES decreased the risk of MACE (HR 0.58, 95% CI 0.34–0.98) [15]. Table 2 lists the clinical trials of women treated with new-generation DES for AMI.

The WIN-DES Collaborative Patient-Level Pooled analysis also studied the safety and efficacy of new-generation DES

Table 2 Randomized controlled trials of acute myocardial infarction in women treated with new-generation drug-eluting stents

Study (type)	Patients (n)	Outcomes (follow-up)	Results
WIN-DES [4••] (26 randomized controlled trials)	11,577 (women); 2176 (AMI)	Long-term safety and efficacy new vs. earlier generation DES (3-years)	New DES = lower death, MI, target lesion revascularization, lower definite/probable stent thrombosis. Durable benefits over 3 years
WIN-DES [15] (26 randomized controlled trials)	11,577 (women); 2176 (AMI)	Long-term safety outcomes new vs. earlier generation DES in unstable/stable angina/AMI (3 years)	New DES = lower MACE. STEMI = increased 3-year mortality in women
WIN-DES [16] (26 randomized controlled trials)	11,577 (women); 2176 (AMI)	Long-term safety outcomes new vs. earlier generation DES in complex vs. non-complex PCI (3 years)	New DES in complex PCI = lower MACE, target lesion revascularization, definite/probable stent thrombosis. Complex PCI: > MACE

WIN-DES, Women in Innovation Initiative-Drug-Eluting Stent Collaborative Patient-Level Pooled Analysis; AMI, acute myocardial infarction; DES, drug-eluting stents; MI, myocardial infarction; MACE, major adverse cardiovascular events; STEMI, ST elevation myocardial infarction; PCI, percutaneous coronary intervention

in women ($n = 10,241$) undergoing complex ($n = 4629$, 45%) or non-complex percutaneous coronary intervention (PCI) [16]. Complex PCI had higher MACE (adjusted HR, 1.63; 95% CI, 1.45–1.83; $p < 0.0001$) in 3-year follow-up. However, new-generation DES in women who underwent complex PCI was associated with a significant reduction in MACE (adjusted HR, 0.81; 95% CI, 0.68–0.96), target lesion revascularization (adjusted HR, 0.74; 95% CI, 0.57–0.95), and definite or probable stent thrombosis (adjusted HR, 0.50; 95% CI, 0.30–0.83).

Moreover, the WIN-DES Collaborative Patient-Level Pooled analysis [5] evaluated the clinical impact of definite stent thrombosis on mortality in women. In 11,557 women, definite stent thrombosis occurred in 105 (0.9%) in a 3-year median follow-up. Independent predictors of stent thrombosis were age (HR, 1.03 per year decrease; 95% CI, 1.00–1.05; $p = 0.041$), diabetes (HR, 2.25; 95% CI, 1.27–3.99; $p = 0.005$), NSTEMI at presentation (HR, 1.97; 95% CI, 1.04–3.75; $p = 0.037$), and stent diameter (HR, 3.76 per mm decrease; 95% CI, 1.66–8.53; $p = 0.002$). The adjusted HR for mortality from stent thrombosis in the first 7 days, 8–30 days, and beyond 30 days was 115.81 (95% CI 68.96–194.47), 37.44 (95% CI 17.31–80.98), and 3.54 (95% CI 2.20–5.69). No difference in stent thrombosis was observed between new- or old-generation DES (HR 0.60; 95% CI 0.33–1.07; $p = 0.087$).

Also, the WIN-DES Collaboration [17] studied the impact of coronary calcification in women undergoing PCI with DES (new and early generation) and found that they have worse clinical profiles with increased risk of ischemia. In the 3-year clinical follow-up, women with moderate or severe coronary calcification ($n = 1622$, 25.5%) compared with none or mild ($n = 4749$, 74.5%) had an increased risk of death, AMI, or target lesion revascularization (18.2% vs. 13.1%; adjusted HR 1.56; 95% CI 1.33–1.84, $p < 0.0001$). Moreover, moderate or severe calcification was associated with greater death, AMI, and stent thrombosis (11.0% vs. 7.5%; adjusted HR 1.48; 95% CI 1.21–1.80, $p < 0.0001$). In another sub-study, women with high atherothrombotic risk factors (history of diabetes, prior PCI or CABG, or prior MI) had a significantly increased risk of MACE (15.8% vs. 10.6%, adjusted HR 1.53; 95% CI 1.34–1.75, $p = 0.006$), cardiac mortality (4.1% vs. 2.1%, adjusted HR 2.35; 95% CI 1.71–3.23, $p < 0.0001$), and all-cause mortality (5.8% vs. 3.4%, adjusted HR 2.10; 95% CI 1.66–2.66, $p < 0.0001$) [18]. The women with high-risk atherothrombotic factors had lower risk of 3-year MACE (adjusted HR 0.69; 95% CI 0.52–0.92) with the new-generation DES compared with early-generation DES. Also, stent thrombosis risk was lower during years 1 to 3 with new-generation DES.

However, limitations exist in the WIN-DES Collaboration since the data was from 26 randomized controlled trials with post hoc analysis. Also, heterogeneity exists amongst the studies. Furthermore, the 26 included trials were not designed specifically to evaluate the safety and efficacy of DES in calcified lesions in

women. Therefore, the aforementioned findings of the WIN-DES collaboration are not definitive, but hypothesis generating. Further studies in women are necessary for conclusive evidence.

Conclusions

Women with AMI may present with atypical clinical symptoms and have late presentations inducing delayed or inadequate AMI treatment. Furthermore, women with AMI may have increased comorbidities with undertreatment of underlying medical conditions. Furthermore, they may have increased risk of major bleeding. Nevertheless, the new-generation DES lowers definite or probable stent thrombosis. It is also associated with durable benefits in women over 3 years. The 2014 AHA/ACC guideline for the management of patients with NSTEMI clearly recommends an urgent/immediate invasive strategy in women with NSTEMI who have refractory angina, hemodynamic or electrical instability, or positive troponin [19]. As new technologies and advances in cardiovascular disease continue, a focus on improving outcomes in women should be considered since the vast majority of AMI literature has involved men. Consequently, further research is desirable in women with cardiovascular disease and AMI.

Compliance with Ethical Standards

Conflict of Interest Subrata Kar declares that he has no conflict of interest.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

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