Outcomes after percutaneous coronary intervention in contemporary Australian practice: insights from a large multicentre registry

Andrew E Ajani, Christopher M Reid, Stephen J Duffy, Nick Andrianopoulos, Jeffrey Lefkovits, Alexander Black, Gishel New, Robert Lew, James A Shaw, Bryan P Yan, Ronen Gurvitch, Ali Al-Fiadh, Angela L Brennan and David J Clark

ABSTRACT

Objective: To examine short- and medium-term outcomes of percutaneous coronary interventions (PCIs), with a focus on comparing drug-eluting stents (DESs) with bare-metal stents (BMSs).

Design, setting and participants: Retrospective analysis of data from the Melbourne Interventional Group (MIG) registry, a large multicentre Australian registry. The study cohort consisted of 6364 consecutive patients undergoing 7167 PCIs between April 2004 and August 2007.

Main outcome measures: Clinical events including death, myocardial infarction (MI), target lesion revascularisation (TLR), target vessel revascularisation (TVR) and major adverse cardiac events (MACE) (a composite of death, MI and TVR), at 30 days and at 12 months.

Results: The cohort was predominantly male (74%), with a mean age of 64.7 years (SD, 12.0 years). DESs were used in 3482 (51.4%) of PCIs. In the overall cohort, rates of clinical events were low at 30 days: mortality (1.9%), MI (2.4%), TLR (2.0%), TVR (2.4%) and MACE (5.7%). At 12 months, event rates were: mortality (5.2%), MI (6.0%), TLR (5.8%), TVR (8.2%) and MACE (16.2%). Patients receiving DESs had similar mortality rates to those receiving BMSs (4.0% v 6.0%; $P = 0.62$ [propensity score-adjusted]); late thrombosis rates were also similar in the two groups (0.8% v 1.1%; $P = 0.38$). The proportion of patients receiving DESs fell significantly over time, from 54.9% in the first 24 months to 44.7% in the last 15 months of the study period ($P < 0.01$). Independent predictors of 12-month mortality included diabetes, renal failure, ST-segment-elevation MI and cardiogenic shock.

Conclusion: Our clinical event rates were comparable with international registry outcomes. Rates of mortality and stent thrombosis were no higher in patients with DESs than those with BMSs. Although DESs were used in about half the procedures (preferentially for higher-risk lesions), recent trends suggest their use is in decline.

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The number of percutaneous coronary interventions (PCIs) performed in Australian hospitals has escalated rapidly in recent years and, since 1997–98, PCI has replaced coronary artery bypass graft surgery as the most common coronary revascularisation treatment for coronary heart disease in Australia.[1] Coronary stents were used in over 90% of these procedures. Drug-eluting stents (DESs), which are coated with antiproliferative agents, have emerged as effective in preventing restenosis.[2-5] While DESs are more effective than bare-metal stents (BMSs) in reducing restenosis,[4,5] recent concerns have arisen about the safety of DESs, which may be associated with a *potential* increased risk of late thrombosis (31–365 days after stent implantation), very late thrombosis (> 12 months after stent implantation), myocardial infarction (MI) and mortality.[6-8] The impact of recent DES controversies emphasises the need for accurate PCI outcome data in the context of an ageing population (with an increasing number of high-risk patients) and rapid evolution of device technology.[9]

The Melbourne Interventional Group (MIG) is a voluntary collaboration of interventional cardiologists practising at eight hospitals (seven public and one private) in Victoria (Box 1).[10] Members of the group contribute data on consecutive patients undergoing PCI to a central registry. Since MIG's inception in April 2004, the registry data have offered an insight into the shifting landscape of local interventional practice.

The aim of our study was to analyse demographic, clinical and procedural characteristics of our PCI population to date and to report on 30-day and 12-month clinical outcomes in eligible patients. Further, we aimed to compare the clinical indications, efficacy and safety outcomes, and changing practice patterns over time in patients treated with either DESs or BMSs.

Abbreviations

BMS	Bare-metal stent
DES	Drug-eluting stent
MACE	Major adverse cardiac events
MI	Myocardial infarction
MIG	Melbourne Interventional Group
PCI	Percutaneous coronary intervention
SCAAR	Swedish Coronary Angiography and Angioplasty Registry
STEMI	ST-segment-elevation myocardial infarction
TLR	Target lesion revascularisation
TVR	Target vessel revascularisation

1 Melbourne Interventional Group (MIG) investigators

The following investigators and institutions participated in the MIG registry: ***Alfred Hospital:*** Duffy SJ, Shaw JA, Walton A, Farrington C, Dart A, Broughton A, Federman J, Keighley C, Butler MJ, Pereira T; ***Austin Hospital:*** Clark DJ, Farouque O, Horrigan M, Johns J, Oliver L, Brennan J, Chan R, Proimos G, Dortimer T, Chan B, Tonkin A, Brown L, Sahar A, Freeman M, Lim HS, Al-Fiadh A, Charter K; ***Box Hill Hospital:*** New G, Roberts L, Rowe M, Proimos G, Cheong Y, Goods C, Teh A, Fernando D, Mah E, Lim CCS, Coller J; ***Frankston Hospital:*** Lew R, Szto G, Teperman R, Templin R; ***Geelong Hospital:*** Black A, Sebastian M, Yip T, Rahman M, Aithal J, Dyson J, Du Plessis T; ***Monash University:*** Krum H, Reid C, Andrianopoulos N, Brennan A, Loane P, Curran L; ***Northern Hospital:*** Van Gaal W, Barlis P, Mehta N, Ponnuthurai L, Miels J, Buckley E. ***Peninsula Private Hospital:*** Szto G, O'Shea V; ***Royal Melbourne Hospital:*** Ajani AE, Warren R, Eccleston D, Lefkovits J, Iyer R, Yan BP, Gurvitch R, Sallaberger M; ***Western Hospital:*** Lim Y-L, Eccleston D, Walton A. ◆

METHODS

Background of the MIG registry

The data for our study were extracted from the MIG registry. Data are recorded prospectively on a standard case report form that includes standardised definitions for all fields.[10] Data elements were incorporated from a number of current interventional databases, including the American College of Cardiology–National Cardiovascular Data Registry.

The registry is coordinated by the Monash Centre for Cardiovascular Research and Education in Therapeutics at Monash University in Melbourne. The case report form has been developed using TeleForm, version 9 (Cardiff, Vista, Calif, USA). Completed forms are faxed to the data centre, verified on receipt, and electronically uploaded into the central database. Thirty-day and 12-month follow-up is performed by a research coordinator at each hospital.

An independent audit was conducted at all enrolling sites by an investigator not affiliated with that institution. Overall data accuracy was determined to be 96.6%.

Procedures and post-intervention follow-up

We examined consecutive PCI procedures between April 2004 and August 2007. We report demographic, clinical and procedural characteristics of the total PCI population enrolled during this period and clinical outcomes in patients eligible for 30-day and 12-month follow-up.

The interventional strategy and stent selection were left to the discretion of the operator in all procedures. Total stent length was used as a surrogate measure for target lesion length, and stent diameter for target vessel diameter. The use of anticoagulants and periprocedural glycoprotein IIb/IIIa inhibitors was determined by the operator. Oral antiplatelet therapy followed current internationally accepted guidelines, which recommend a combination of aspirin and clopidogrel for a minimum of 4 weeks for patients with BMSs and 6–12 months for patients with DESs.[11]

We compared patients according to stent type. Patients were included in the DES group if they had at least one DES implanted, while those in the BMS group had exclusively BMSs implanted. We examined rates of and indications for DES use, as well as trends in DES use over time. This was considered pertinent, given recent concerns about potential increased rates of stent thrombosis (and/or MI and mortality) in patients with DESs.[6-8] Criteria for the use of DESs, which were consistent at all participating public hospitals, were based on clinical guidelines developed in 2003 by the Victorian Department of Human Services.[12]

These criteria included having one or more of the following: diabetes mellitus, target vessel diameter $\leqslant 2.5$ mm, target lesion length $\geqslant 20$ mm, bifurcation lesion, ostial lesion, in-stent restenosis and chronic total occlusions.

Clinical endpoints

In-hospital complications were recorded at the time of hospital discharge. All cardiac events were documented, including death, MI, target lesion revascularisation (TLR, defined as revascularisation within 5 mm of a previously treated lesion), target vessel revascularisation (TVR, defined as revascularisation of a previously treated coronary artery), and composite major adverse cardiac events (MACE, comprising death, MI and TVR). Late thrombosis (31–365 days after stent implantation) was defined as "definite" if it satisfied the Academic Research Consortium definition (ie, angiographic or autopsy evidence of thrombus or occlusion in the presence of acute coronary syndrome).[13] Patient medical records were reviewed to substantiate recorded events.

2 Baseline characteristics of patients in the Melbourne Interventional Group (MIG) cohort

	Overall*	DES group	BMS group	*P*
Number of procedures, *n* (%)	7167	3482 (51.4†)	3294 (48.6†)	0.02
Mean age in years (SD)	64.7 (12.0)	65.0 (11.9)	64.3 (12.0)	0.02
Males, *n* (%)	5299 (73.9)	2572 (73.9)	2439 (74.0)	0.87
Diabetes mellitus, *n* (%)	1708 (23.8)	1054 (30.3)	557 (16.9)	< 0.01
Hypertension, *n* (%)	4550 (63.6)	2269 (65.3)	2023 (61.5)	< 0.01
Hypercholesterolaemia, *n* (%)	5076 (71.3)	2516 (72.6)	2272 (69.6)	0.01
Past or current smoker, *n* (%)	4613 (65.4)	2217 (62.1)	2260 (69.2)	< 0.01
Mean BMI (kg/m^2) (SD)	28.1 (5.0)	28.0 (4.8)	28.2 (5.1)	0.27
Mean LVEF (SD)	55.4 (12.4)	55.7 (12.4)	55.3 (12.3)	0.27
History				
Myocardial infarction, *n* (%)	2153 (30.1)	1151 (33.1)	841 (25.6)	< 0.01
PCI, *n* (%)	1730 (24.2)	1006 (28.9)	570 (17.3)	< 0.01
Congestive cardiac failure, *n* (%)	271 (3.8)	149 (4.3)	103 (3.1)	0.01
Cerebrovascular disease, *n* (%)	399 (5.6)	185 (5.3)	189 (5.7)	0.45
COPD, *n* (%)	334 (4.7)	133 (3.9)	186 (5.7)	< 0.01
Peripheral vascular disease, *n* (%)	479 (6.7)	256 (7.4)	183 (5.6)	< 0.01
Renal impairment (creatinine level > 0.2 mmol/L), *n* (%)	277 (3.9)	149 (4.3)	113 (3.4)	0.07
Clinical presentation				
Stable angina, *n* (%)	2290 (32.2)	1187 (34.2)	945 (29.0)	< 0.01
Unstable angina, *n* (%)	1058 (14.9)	586 (16.8)	422 (12.8)	< 0.01
STEMI, *n* (%)	1640 (23.1)	607 (17.4)	948 (28.8)	< 0.01
NSTEMI, *n* (%)	1651 (23.2)	803 (23.1)	778 (23.6)	0.59
Asymptomatic/atypical chest pain, *n* (%)	475 (6.7)	287 (8.2)	164 (5.0)	< 0.01
Cardiogenic shock, *n* (%)	162 (2.3)	44 (1.3)	104 (3.2)	< 0.01
STEMI Killip class‡				
III (%)	62 (1.3)	29 (1.3)	31 (1.3)	0.98
IV (%)	109 (2.3)	34 (1.5)	64 (2.7)	< 0.01

BMI = body mass index. BMS = bare-metal stent. COPD = chronic obstructive pulmonary disease. DES = drug-eluting stent. LVEF = left ventricular ejection fraction. PCI = percutaneous coronary intervention. STEMI = ST-segment-elevation myocardial infarction. NSTEMI = non-STEMI.
* For all PCIs in the MIG cohort. † Proportion of total number of stent implantation procedures ($n = 6776$).
‡ Class III (acute pulmonary oedema); class IV (cardiogenic shock). ◆

Statistical analysis

Continuous variables were summarised as means and SDs and compared using Student *t* tests. Categorical data were summarised as percentages and compared using Fisher's exact or χ^2 tests. A propensity score for the BMS group versus the DES group was developed using a logistic model incorporating 37 variables. The model fitted 89.7% of available PCIs, and the C-statistic was 0.87.

Univariate logistic regression identified 25 variables ($P < 0.1$) that were included along with the propensity score in a multivariate logistic regression analysis to determine independent predictors of death and TVR at 12-month follow-up. Two-sided *P* values of < 0.05 were considered statistically significant.

Ethical approval and patient consent

Ethical approval for our study was obtained from the human research ethics committees of all participating hospitals. The MIG registry employs an "opt-out consent", which requires patients to actively decline to contribute their relevant information. This model has been used effectively for the Australian National Cardiac Surgery Database.[14]

3 Lesion and procedural characteristics relating to patients in the Melbourne Interventional Group (MIG) cohort

	Overall*	DES group	BMS group	*P*
Number of lesions, *n* (%)	8751	4503 (54.7†)	3731 (45.3†)	< 0.01
Type, ACC/AHA lesion morphology[15]				
A, *n* (%)	1150 (13.1)	522 (11.6)	604 (16.2)	< 0.01
B1, *n* (%)	3338 (38.0)	1622 (36.0)	1572 (42.1)	< 0.01
B2/C, *n* (%)	4263 (48.5)	2327 (51.7)	1540 (41.3)	< 0.01
De novo, *n* (%)	8300 (94.6)	4165 (92.5)	3686 (98.8)	< 0.01
Restenosis, *n* (%)	55 (0.6)‡	32 (0.7)	13 (0.3)	0.03
In-stent restenosis, *n* (%)	421 (4.8)‡	305 (6.8)	27 (0.7)	< 0.01
Target vessel				
Left main coronary artery, *n* (%)	73 (0.8)	46 (1.0)	21 (0.6)	0.02
Left anterior descending artery, *n* (%)	2880 (32.8)	1597 (35.5)	1161 (31.1)	< 0.01
Right coronary artery, *n* (%)	2796 (31.8)	1150 (25.5)	1481 (39.7)	< 0.01
Circumflex artery, *n* (%)	1216 (13.8)	588 (13.1)	564 (15.1)	< 0.01
Bypass grafts, *n* (%)	255 (2.9)	160 (3.6)	89 (2.4)	< 0.01
Multivessel disease, *n* (%)	2678 (58.1)	1346 (62.7)	1170 (52.3)	< 0.01
Mean total stent length in mm (SD)	16.6 (5.3)	17.7 (6.0)	15.4 (4.2)	< 0.01
Stent length ≥ 20 mm, *n* (%)	2499 (28.4)	1689 (37.5)	809 (21.7)	< 0.01
Mean stent diameter in mm (SD)	2.9 (0.5)	2.8 (0.4)	3.1 (0.5)	< 0.01
Stent diameter ≤ 2.5 mm, *n* (%)	2482 (28.2)	1766 (39.2)	591 (15.8)	< 0.01
Glycoprotein IIb/IIIa use, *n* (%)	1934 (27.0)	874 (25.1)	970 (29.4)	< 0.01
Procedural success, *n* (%)	5436 (96.4)	2735 (99.0)	2519 (99.6)	< 0.01

ACC/AHA = American College of Cardiology/American Heart Association. BMS = bare-metal stent. DES = drug-eluting stent. * For all lesions in MIG cohort patients. † Proportion of total number of stents used in patients receiving stents. ‡ Some restenosis cases may have been included in the in-stent restenosis category (ie, there may be some overlap between these two categories). ◆

4 Clinical events at 30 days and 12 months among patients in the Melbourne Interventional Group (MIG) cohort

	Overall*	DES group	BMS group	Unadjusted OR (95% CI) (BMS v DES)	*P*	Propensity score-adjusted OR (95% CI) (BMS v DES)	*P*
30 days							
Number of PCIs followed up, *n* (%)	6787 (94.7)	3307 (51.6†)	3108 (48.4†)				
Death, *n* (%)	128 (1.9)	41 (1.2)	68 (2.2)	0.56 (0.38–0.83)	< 0.01	0.83 (0.50–1.37)	0.47
Myocardial infarction, *n* (%)	163 (2.4)	84 (2.5)	65 (2.1)	1.22 (0.86–1.71)	0.23	1.02 (0.66–1.57)	0.93
TLR, *n* (%)	137 (2.0)	53 (1.6)	45 (1.4)	1.19 (0.79–1.79)	0.41	1.30 (0.81–2.08)	0.28
TVR, *n* (%)	161 (2.4)	60 (1.8)	51 (1.6)	1.18 (0.80–1.73)	0.40	1.41 (0.86–2.33)	0.18
MACE, *n* (%)	390 (5.7)	159 (4.8)	154 (5.0)	0.96 (0.77–1.21)	0.75	1.11 (0.83–1.51)	0.47
12 months							
Number of PCIs followed up, *n* (%)	4253 (59.0)	2157 (54.0†)	1840 (46.0†)				
Death, *n* (%)	220 (5.2)	86 (4.0)	110 (6.0)	0.65 (0.49–0.87)	< 0.01	0.82 (0.56–1.20)	0.31
Myocardial infarction, *n* (%)	255 (6.0)	130 (6.0)	105 (5.7)	1.10 (0.84–1.46)	0.67	0.80 (0.57–1.13)	0.21
TLR, *n* (%)	248 (5.8)	91 (4.2)	110 (6.0)	0.69 (0.52–0.92)	0.01	0.57 (0.39–0.82)	< 0.01
TVR, *n* (%)	347 (8.2)	138 (6.4)	136 (7.4)	0.84 (0.66–1.08)	0.17	0.66 (0.48–0.90)	0.01
MACE, *n* (%)	691 (16.2)	296 (13.7)	290 (15.8)	0.85 (0.71–1.01)	0.07	0.75 (0.60–0.94)	0.01
Late thrombosis,‡ *n* (%)	36 (0.8)	16 (0.8)	18 (1.1)	0.74 (0.38–1.46)	0.39	0.55 (0.23–1.29)	0.17

BMS = bare-metal stent. DES = drug-eluting stent. MACE = major adverse cardiac events. OR = odds ratio. PCI = percutaneous coronary intervention. TLR = target lesion revascularisation. TVR = target vessel revascularisation.* For all PCIs followed up in the MIG cohort. † Proportion of total number of PCIs followed up in patients receiving stents. ‡ "Definite" late thrombosis according to the Academic Research Consortium definition.[13] ◆

RESULTS

Overall cohort

The overall MIG cohort comprised 6364 patients who underwent 7167 coronary interventions. Patients were predominantly men (74%), with a mean age of 64.7 years (SD, 12.0 years) (Box 2). The majority of procedures were performed for acute coronary syndromes (61.2%), mainly ST-segment-elevation MI (STEMI) (23.1%) and non-STEMI (23.2%). Most lesions were de novo lesions (94.6%), and a significant proportion were complex lesions (48.5% type B2/C) (Box 3).[15] The mean stent length was 16.6 mm (SD, 5.3 mm) and the mean stent diameter was 2.9 mm (SD, 0.5 mm).

Clinical outcomes of overall cohort

In-hospital events for the total cohort included mortality (1.5%), MI (1.5%), emergency PCI (0.8%) and coronary artery bypass graft surgery (0.8%). The frequency of PCI complications, such as coronary perforation (0.2%), cardiac tamponade (0.2%) and major bleeding (1.8%), was low.

At 30 days, follow-up of 6787 procedures (94.7%) revealed a mortality rate of 1.9%, a recurrent MI rate of 2.4% and a TVR rate of 2.4%, with an overall MACE rate of 5.7% (Box 4).

At 12 months, follow-up of 4253/4760 procedures (ie, 95% of procedures performed to August 2006) revealed a mortality rate of 5.2%, an MI rate of 6.0%, a TVR rate of 8.2% and a MACE rate of 16.2%.

Independent predictors of mortality at 12 months included cardiogenic shock at presentation (odds ratio [OR], 10.5 [95% CI, 5.1–21.6]; $P < 0.01$); renal failure (OR, 3.62 [95% CI, 2.22–5.90]; $P < 0.01$); STEMI (OR, 2.15 [95% CI, 1.36–3.38]; $P < 0.01$); history of congestive heart failure (OR, 2.1 [95% CI, 1.16–3.79]; $P = 0.02$); chronic obstructive pulmonary disease (OR, 1.95 [95% CI, 1.13–3.37]; $P = 0.02$); peripheral vascular disease (OR, 1.84 [95% CI, 1.09–3.10]; $P = 0.02$); diabetes (OR, 1.58 [95% CI, 1.09–2.29]; $P = 0.02$); and increasing age (OR, 1.05 [95% CI, 1.03–1.06]; $P < 0.01$).

Independent predictors of TVR at 12 months included in-stent restenosis (OR, 2.87 [95% CI, 1.78–4.64]; $P < 0.01$); smaller vessels (OR, 1.85 [95% CI, 1.41–2.44]; $P < 0.01$); BMS use (OR, 1.64 [95% CI, 1.23–2.17]; $P < 0.01$); and diabetes (OR, 1.39 [95% CI, 1.03–1.86]; $P = 0.03$).

Comparison of DESs and BMSs

Coronary stenting was performed in 6940 of 7167 procedures (96.8%). DESs were used in 3482 (51.4%) and BMSs in 3294 (48.6%) of these procedures during the study period. High-risk characteristics were more commonly seen in the DES cohort than the BMS cohort, including increased age (65.0 years [SD, 11.9 years] v 64.3 years [SD, 12.0 years]; $P = 0.02$) and diabetes (30.3% v 16.9% of patients; $P < 0.01$). The exceptions to this were patients who presented with STEMI (17.4% v 28.8%; $P < 0.01$) or cardiogenic shock (1.3% v 3.2%; $P < 0.01$), who were less likely to receive a DES than a BMS.

In accordance with the abovementioned criteria for DES use, patients with more complex lesion subsets were more likely to receive DESs. DESs were more likely to be used than BMSs for type B2/C lesions (51.7% v 41.3% of lesions; $P < 0.01$) and in longer lesions (17.7 mm [SD, 6.0 mm] v 15.4 mm [SD, 4.2 mm]; $P < 0.01$).

Clinical outcomes for DESs versus BMSs

The in-hospital mortality rate was higher in the BMS cohort than the DES cohort (1.7% v 0.9%; $P < 0.01$). At 30-day follow-up, the adjusted mortality rate (1.2% in the DES cohort v 2.2% in the BMS cohort; $P = 0.47$) and MACE rate (4.8% in the DES cohort v 5.0% in the BMS cohort; $P = 0.47$) were not significantly different between the two groups (Box 4). At 12-month follow-up, patients in the DES and BMS cohorts had similar adjusted mortality rates (4.0% v 6.0%; $P = 0.31$), but the DES group had lower rates of TVR (6.4% v 7.4%; $P = 0.01$) and MACE (13.7% v 15.8%; $P = 0.01$). MI rates were similar in both cohorts at 30 days and at 12 months, as were rates of late thrombosis.

Trends in stent use over the time period of our study were analysed. DES use as a proportion of total stent use fell from 54.9% in the period April 2004–May 2006 to 44.7% in the last 15 months of the study (June 2006–August 2007) ($P < 0.01$). In the last quarter (June 2007–August 2007), the use of DESs had decreased further to 37.2%, the lowest quarterly rate of DES use since the inception of the MIG registry. This correlated with concerns in the interventional community about the potential increased risk of late and very late thrombosis with the use of DESs.

The adjusted propensity score for DESs versus BMSs for 12-month mortality (OR, 0.82 [95% CI, 0.56–1.20]; $P = 0.31$) suggests that stent type did not influence mortality. The adjusted propensity score for DESs versus BMSs for 12-month TVR (OR, 0.66 [95% CI, 0.48–0.90]; $P < 0.01$) supports the advantage of DESs over BMSs in reducing clinical restenosis.

Pharmacotherapy in the PCI population

The use of cardiac medications, including antiplatelet agents and statins, was consist-

5 Pharmacotherapy at 30 days and 12 months among patients in the Melbourne Interventional Group cohort

	Overall	DES group	BMS group	*P*
30 days				
Number of PCIs followed up, *n* (%)	6787 (94.7)	3307 (51.6*)	3108 (48.4*)	0.11
Aspirin, *n* (%)	6040 (94.2)	2999 (94.5)	2727 (94.0)	0.42
Clopidogrel, *n* (%)	5810 (90.9)	3017 (95.1)	2586 (89.7)	< 0.01
Statins, *n* (%)	5711 (89.7)	2790 (88.4)	2622 (91.2)	< 0.01
β-Blockers, *n* (%)	4183 (65.9)	2024 (64.2)	1931 (67.6)	< 0.01
ACE inhibitors, *n* (%)	3827 (60.3)	1873 (59.4)	1772 (62.0)	0.04
12 months				
Number of PCIs followed up, *n* (%)	4253 (95)	2157 (54.0*)	1840 (46.0*)	< 0.01
Aspirin, *n* (%)	3300 (87.6)	1714 (87.2)	1416 (88.4)	0.27
Clopidogrel, *n* (%)	2131 (56.9)	1303 (66.4)	746 (47.0)	< 0.01
Statins, *n* (%)	3292 (87.8)	1724 (88.0)	1400 (87.9)	0.95
β-Blockers, *n* (%)	2172 (58.2)	1128 (57.8)	929 (58.7)	0.56
ACE inhibitors, *n* (%)	2080 (55.8)	1077 (55.2)	903 (57.2)	0.23

ACE = angiotensin-converting enzyme. BMS = bare-metal stent. DES = drug-eluting stent. PCI = percutaneous coronary intervention. * Proportion of total number of PCIs followed up in patients receiving stents.

ently high in the overall cohort and in the two stent groups (Box 5). Usage rates were maintained from 30-day to 12-month follow-up, reflecting reasonable longer term compliance. Patients with DESs were more likely to be receiving clopidogrel than patients with BMSs at both 30 days (95.1% v 89.7%; $P < 0.01$) and 12 months (66.4% v 47%; $P < 0.01$). The rates of use of β-blockers and angiotensin-converting enzyme (ACE) inhibitors were lower than expected at both 30 days and 12 months.

DISCUSSION

Our study represents the largest contemporary multicentre analysis of PCIs in Australia. The data depict clinical outcomes from a "real world" population of consecutive patients, and reflect a more challenging cohort of patients than those included in randomised controlled trials.[4,5,16-19] A high proportion of patients in the MIG cohort presented with acute coronary syndromes and complex lesions (eg, type B2/C). About half of all procedures involved implantation of DESs, and their use was driven by predefined clinical criteria that are linked to funding. While the DES and BMS groups were non-randomised, it is not surprising that clinical event rates were largely comparable, as higher-risk lesions were preferentially treated with DESs (the success of which is primarily driven by a reduction in restenosis).

In general, our demographic and procedural variables as well as clinical outcomes compare favourably with data from other PCI registries such as the Ontario registry[20] and the Swedish Coronary Angiography and Angioplasty Registry (SCAAR).[21] Our 12-month mortality rates were lower in patients receiving DESs than those receiving BMSs — concurring with Ontario PCI registry data but not SCAAR data. Higher mortality in our BMS cohort compared with our DES cohort probably reflects the preferential use of BMSs in patients presenting with STEMI and cardiogenic shock. SCAAR data showed that the DES cohort had an absolute increase of 0.5% in the risk of death per year (after the initial 6 months), yet these results were not sustained at 4-year follow-up, highlighting the uncertainty of late outcomes with DESs. Our relatively low rates of 12-month revascularisation in both DES and BMS groups (6.4% and 7.4%, respectively) are also comparable with Ontario registry rates (5.2% and 8.2%, respectively[20]). These low rates of TVR contrast with rates of over 15% reported in other clinical trials of DESs.[22,23]

While most DES studies have reported a high level of stent safety, emerging evidence of late and very late stent thrombosis, MI and mortality has challenged earlier safety claims.[24-27] This evidence has been intensely debated and has prompted many physicians to take a cautious approach in selecting patients for DES implantation. This trend is highlighted by the 19% reduction in DES use over the last 15 months of MIG registry data analysed. Indeed, when assessing DES use in the last quarter, the reduction was 32% compared with the early MIG registry data. Our selection of patients for DESs remains focused on those at highest risk of restenosis who should be tolerant of appropriate antiplatelet therapy. The rate of use of DESs in the long term remains uncertain, and will be strongly influenced by the efficacy/safety balance of newer-generation DESs.

Our analysis of pharmacological treatment showed that compliance in taking medications from the major drug classes was maintained between 30-day and 12-month follow-up. Dual antiplatelet therapy (aspirin and clopidogrel) was, as expected, almost universally prescribed up to 30 days after stent implantation. Surprisingly, 34% of DES patients were not taking clopidogrel at 12 months, despite the minimum of 12 months' uninterrupted dual therapy recommended by the updated American Heart Association/American College of Cardiology guidelines for patients at low risk of bleeding.[28] (The optimal duration of dual antiplatelet therapy remains uncertain.) In contrast, 47% of BMS patients remained on clopidogrel at 12 months. A substantial proportion of our registry patients were not receiving β-blockers or ACE inhibitors, despite appropriate cardiovascular indications (specifically, patient subsets such as those over 80 years of age and those with renal impairment).

Our study has several limitations. Firstly, as not all Victorian public hospitals were represented, our findings may not reflect DES use and other practices in non-participating hospitals. Secondly, despite inherent limitations of registry data, PCI registries such as the MIG allow appraisal of low-frequency clinical events such as late thrombosis. Sample sizes in randomised controlled trials are often inadequate to analyse these less common, but potentially serious, adverse outcomes.[29,30] Finally, 12-month follow-up was incomplete, although our sample represented 95% of eligible patients based on the date of index procedure. Annual follow-up is planned beyond 12 months up to 5 years using the National Death Index, as we believe this is critical in view of concerns about very late events after DES implantation.

CONCLUSION

The MIG registry is the largest contemporary multicentre registry of coronary interventions in Australia, and reflects a "real world", challenging population. Overall clinical event rates were largely comparable with outcomes reported from international registries. While DESs appear safe and were used in half of the procedures (preferentially for higher-risk lesions), recent trends suggest their use is declining.

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COMPETING INTERESTS

None identified.

AUTHOR DETAILS

Andrew E Ajani, MD, FRACP, FJFICM, Interventional Cardiologist and Director, Coronary Care Unit[1]
Christopher M Reid, BA, MSc, PhD, Associate Professor and Associate Director[2]
Stephen J Duffy, FRACP, MRCP, PhD, Head, Cardiology General Services[3]
Nick Andrianopoulos, MB BS, MBiostat, Research Fellow[2]
Jeffrey Lefkovits, MB BS, FRACP, Interventional Cardiologist[1]
Alexander Black, MB BS, FRACP, Director of Cardiology[4]
Gishel New, FRACP, FACC, PhD, Director of Cardiology[5]
Robert Lew, MB BS, FRACP, PhD, Interventional Cardiologist[6]
James A Shaw, MB BS, FRACP, PhD, Interventional Cardiologist[3]
Bryan P Yan, MB BS, FRACP, Interventional Cardiology Fellow[7]
Ronen Gurvitch, MB BS, Interventional Cardiology Fellow[1]
Ali Al-Fiadh, MB BS, Interventional Cardiology Fellow[8]
Angela L Brennan, RN, CCRN, Research Fellow[2]
David J Clark, MB BS, FRACP, Interventional Cardiologist[8]

1 Royal Melbourne Hospital and University of Melbourne, Melbourne, VIC.
2 Centre for Cardiovascular Research and Education in Therapeutics, Department of Epidemiology and Preventive Medicine, Monash University, Melbourne, VIC.
3 Alfred Hospital, Melbourne, VIC.
4 Geelong Hospital, Geelong, VIC.
5 Box Hill Hospital, Melbourne, VIC.
6 Frankston Hospital, Melbourne, VIC.
7 Massachusetts General Hospital and Harvard Medical School, Boston, Mass, USA.
8 Austin Hospital, Melbourne, VIC.
Correspondence: andrew.ajani@mh.org.au

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