Use of drug-eluting stents in Victorian public hospitals

Bryan P Yan, Andrew E Ajani, Stephen J Duffy, Gishel New, Mark Horrigan, Gregory Szto, Antony Walton, David Eccleston, Jeffery Lefkovits, Alexander Black, Martin Sebastian, Angela L Brennan, Christopher M Reid and David J Clark
on behalf of the Melbourne Interventional Group (MIG) investigators

ABSTRACT

Objective: We aimed to assess the pattern of use of drug-eluting stents (DESs) in patients undergoing percutaneous coronary interventions (PCIs) in Victorian public hospitals.

Design, setting and patients: Prospective study comparing the use of one or more DESs versus bare-metal stents (BMSs) only, in consecutive patients undergoing 2428 PCIs with stent implantation from 1 April 2004 to 31 December 2005 at seven Victorian public hospitals.

Main outcome measures: Adherence to current Victorian Department of Human Services guidelines which recommend DES use in patients with high-risk features for restenosis (diabetes, small vessels, long lesions, in-stent restenotic lesions, chronic total occlusions and bifurcation lesions).

Results: Of the 2428 PCIs performed, at least one DES was implanted in 1101 (45.3%) and BMSs only were implanted in 1327 (54.7%). In 87.7% (966/1101) of PCI with DESs, there was at least one criterion for high risk of restenosis. DESs were more likely to be used in patients with diabetes (risk ratio [RR], 2.45; 95% CI, 2.02–2.97), small vessels (RR, 3.35; 95%CI, 2.35–4.76), long lesions (RR, 3.87; 95% CI, 3.23–4.65), in-stent restenotic lesions (RR, 3.98; 95%CI, 2.67–6.06), chronic total occlusions (RR, 1.30; 95% CI, 0.51–2.88) and bifurcation lesions (RR, 2.23; 95%CI, 1.57–3.17). However, 66.2% (1608/2428) of all PCIs were in patients eligible for DESs according to Victorian guidelines, and in 39.9% (642/1608) of these PCIs, a BMS was used.

Conclusion: In Victorian public hospitals, DESs have been largely reserved for patients at high risk of restenosis in accordance with Department of Human Services guidelines. However, many patients with high-risk criteria for restenosis did not receive DESs. Greater use of DESs in these patients may improve outcomes by reducing the need for repeat revascularisation.

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Stent implantation has significantly improved the short-term and long-term outcomes of patients undergoing percutaneous coronary interventions (PCIs) for obstructive coronary artery disease compared with balloon angioplasty alone.[1] However, in-stent restenosis may lead to recurrent ischaemia and repeat intervention at rates approaching 30% in high-risk patient subgroups, including those with diabetes, long lesions and small vessels.[2-4] Recently, drug-eluting stents (DESs) that are impregnated with anti-proliferative agents have emerged as an effective strategy in preventing restenosis.[5,6] In two large randomised controlled trials evaluating stents eluting paclitaxel and sirolimus, there was about a 50% reduction in the rate of target vessel failure (defined by death, myocardial infarction, or patients having undergone target vessel revascularisation) in patients receiving DESs compared with conventional bare-metal stents (BMSs).[7,8]

In Australia, the cost of DESs is about three to four times that of conventional BMSs. As a result, DES use in the public health system is not ubiquitous, but is reserved for selected cases. This restriction does not apply to private patients because DESs can be claimed as a prosthesis from their insurance fund.

In Victorian public hospitals, the Department of Human Services has provided funding for DESs in 30%–40% of PCI cases. DESs are therefore reserved for patients at high risk of restenosis, who will theoretically derive the greatest benefit. Current Department of Human Services indications for DESs in Victorian public hospitals are listed below in the Methods.

We aimed to evaluate the use of DESs in patients undergoing PCI in Victorian public hospitals, and whether DESs were implanted in patients at high risk of restenosis in accordance with Department of Human Services guidelines.

METHODS

We examined PCI with stent implantation procedures in consecutive patients between 1 April 2004 and 31 December 2005 at seven Victorian public hospitals.

Our data were part of those collected for the Melbourne Interventional Group registry. This registry is a voluntary, collaborative venture by interventional cardiologists practising at these seven hospitals, designed to record data pertaining to PCI and to perform long-term follow-up. Demographic, clinical and procedural characteristics of consecutive patients undergoing PCI are prospectively recorded on a standard case report form with standardised definitions for all fields.[9] The registry is coordinated by the Centre of Clinical Research Excellence in Therapeutics, a research body within the Department of Epidemiology and Preventive Medicine at Monash University, Melbourne. Case record forms for the collection of registry data have 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. A query system has been developed to identify missing data, data inconsistencies and out-of-range values. The database is built on a Microsoft SQL Server platform (Microsoft Corporation, Redmond, Wash, USA) with a Microsoft Access (Microsoft Corporation, Redmond, Wash, USA) user interface.

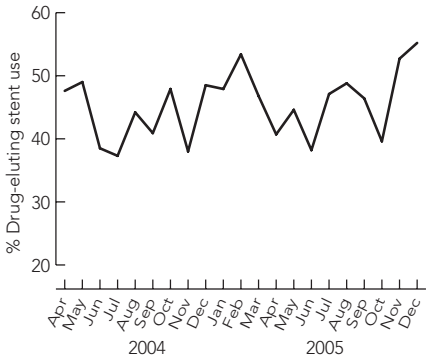
The study population was classified into two groups based on stent type used — patients in the DES group had at least one DES used, while those in the BMS group had only BMSs implanted. Patients were excluded if no stent was used, or if they had private health insurance (to avoid stent selection bias as DESs are fully reimbursed in these patients).

The study protocol was approved by the ethics committee in each participating hospital. "Opt-out" informed consent was obtained in all patients, as previously described.[9]

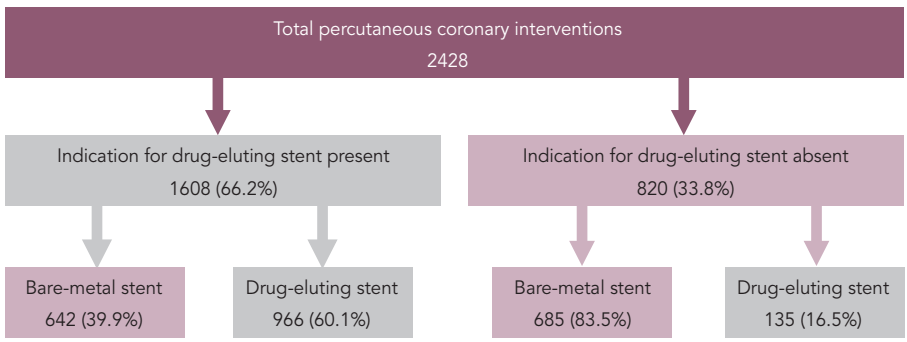
Procedures and post-intervention medications

The interventional strategy and stent selection was 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

1 Drug-eluting stent use per month, 1 April 2004 to 31 December 2005



2 Stent use according to whether percutaneous coronary interventions met Victorian Department of Human Services criteria for implanting drug-eluting stents



diameter. Periprocedural glycoprotein IIb/IIIa inhibitors were used according to the operator's decision. Oral antiplatelet therapy followed current internationally accepted guidelines, which recommend combination of aspirin and clopidogrel for a minimum of 4 weeks for BMSs and for 6–12 months for DESs.[10]

Criteria for use of drug-eluting stents

In 2003, the Victorian Department of Human Services, with the aid of a working group of cardiologists from all hospitals performing PCI, developed clinical guidelines for use of DESs in public hospitals. The resulting criteria for use of DESs included one or more of the following: (i) diabetes mellitus; (ii) target vessel diameter $\leqslant 2.5$ mm; (iii) target lesion length $\geqslant 20$ mm; (iv) bifurcation lesion; (v) ostial lesion; (vi) in-stent restenosis; and (vii) chronic total occlusions. These guidelines were displayed in all cardiac catheter laboratories of Victorian public hospitals, and the reason for DES use was documented in all PCIs.

Statistical analysis

Continuous variables were expressed as mean ± SD, and categorical data expressed as percentages. Continuous variables were compared by means of Student t tests, and categorical variables were compared by means of Fisher exact or χ^2 tests and presented as risk ratios (RR) with 95% CIs. All P values < 0.05 were considered statistically significant.

RESULTS

There were 2428 PCI procedures, with stent implantation in 2976 coronary artery lesions during the study period. Of the 2428 PCIs, 1101 (45.3%) involved insertion of at least one DES, and BMSs were inserted in the remaining 1327 (54.7%). The proportion of DES use was stable over the study period (Box 1). The rates of PCI involving BMSs and DESs according to whether Department of Human Services criteria for DESs were present are shown (Box 2). In 87.7% of PCIs in which DESs were implanted (966/1101), there was at least one Department of Human Services criterion for DES use. However, of the total 2428 PCIs, 1608 (66.2%) were eligible for a DES according to Department of Human Services criteria, and in 642 (39.9%) of these procedures in patients at high-risk of restenosis, only BMSs were used.

Characteristics of patients and procedures associated with DES use

Patients treated with DESs had more diabetes (32.5% v 16.5%; $P < 0.01$), previous myocardial infarction (30.8% v 27.4%; $P = 0.04$)

3 Baseline characteristics of patients undergoing percutaneous coronary intervention (PCI)

	Drug-eluting stents	Bare-metal stents	*P*
Number of PCIs performed	1101 (45.3%)	1327 (54.7)	—
Patient characteristics			
Age (±SD)	64.1 ±12 years	64.3 ±12 years	0.77
Mean LVEF (±SD)	57.2% ±14.5%	56.5% ±13.6%	0.47
Sex (proportion male)	73.8%	73.1%	0.38
Diabetes	32.5%	16.5%	< 0.01
Insulin requiring	7.2%	3.0%	< 0.01
Hypertension	60.3%	62.3%	0.17
Hypercholesterolaemia	70.0%	71.0%	0.31
Smoking	72.4%	77.3%	0.01
Previous myocardial infarction	30.8%	27.4%	0.04
Previous PCI	26.8%	18.8%	< 0.01
Previous CABG	10.3%	6.3%	< 0.01
Moderate to severe renal dysfunction (creatinine > 0.20 mmol/L)	3.3%	2.4%	0.13
Clinical presentation			
Total acute coronary syndromes	59.8%	63.2%	0.06
Unstable angina	19.0%	19.6%	0.20
Non-STEMI	23.3%	21.2%	0.71
STEMI	17.5%	23.3%	0.01
Cardiogenic shock	0.9%	1.4%	0.22

LVEF = left ventricular ejection fraction; CABG = coronary artery bypass grafting; STEMI = ST-elevation myocardial infarction. ◆

4 Characteristics of percutaneous coronary intervention procedures

	Drug-eluting stents	Bare-metal stents	*P*
Number of lesions	1309 (44%)	1667 (56%)	—
Target vessel			
Left main coronary artery	1.1%	0.5%	< 0.01
Left anterior descending artery	37.7%	27.7%	< 0.01
Proximal left anterior descending artery	17.6%	12.5%	< 0.01
Bypass graft	3.3%	1.5%	< 0.01
Mean stent diameter (mm ± SD)	2.78 ± 0.37	3.07 ± 0.5	< 0.01
Stent diameter ⩽ 2.5 mm	45.2%	17%	< 0.01
Mean stent length (mm ± SD)	20.1 ± 8.2	17.2 ± 7.6	< 0.01
Total stent length ⩾ 20 mm	46.9%	17.3%	< 0.01
ACC/AHA lesion type B2/C	55.0%	41.3%	< 0.01
Chronic total occlusion	1.4%	0.8%	< 0.01
Ostial lesions	2.2%	2.2%	0.89
Bifurcation lesions	8.6%	5.6%	0.02
In-stent restenosis	7.9%	2.0%	< 0.01
Glycoprotein IIb/IIIa inhibitor use	27.6%	29.3%	0.16

ACC/AHA = American College of Cardiology/American Heart Association. ◆

5 Rate of drug-eluting stent use in high-risk subgroups and associated risk ratios

Characteristic	Drug-eluting stent use/total PCIs	Risk ratio (95% CI)
In-stent restenosis	93/123 (75.6%)	3.98 (2.67–6.06)
Total stent length ⩾ 20 mm	520/769 (67.6%)	3.87 (3.23–4.65)
Stent diameter ⩽ 2.5 mm	474/693 (68.4%)	3.35 (2.35–4.76)
Diabetes	358/576 (62.2%)	2.45 (2.02–2.97)
Bifurcation lesion	92/144 (63.9%)	2.23 (1.57–3.17)
Ostial lesion	19/34 (55.9%)	1.53 (0.78–3.03)
Chronic total occlusion	13/25 (52.0%)	1.30 (0.51–2.88)

PCI = percutaneous coronary intervention. ◆

6 Likelihood of receiving drug-eluting stents according to number of criteria satisfied

Number of criteria	Risk ratio (95% CI)
1	1.34 (1.14–1.58)
2	4.52 (3.61–5.68)
3 or more	10.41 (6.13–17.5)

and previous coronary artery bypass graft (10.3% v 6.3%; $P < 0.01$) than those in whom only BMSs were used (Box 3). A greater proportion of left-anterior-descending artery and left-main-stem lesions were treated with DESs compared with BMSs (37.7% v 27.7%; $P < 0.01$ and 1.1% v 0.5%; $P < 0.01$, respectively). More lesions treated with DESs were complex (American College of Cardiology/American Heart Association, type B2/C lesions) than those treated with BMSs (55% v 41.3%; $P < 0.01$). More DESs than BMSs were implanted in small vessels (⩽ 2.5 mm stents; 45.2% v 17%; $P < 0.01$), long lesions requiring 20 mm or more in length of stent (46.9% v 17.3%; $P < 0.01$), chronic total occlusions (1.4% v 0.8%; $P < 0.01$), bifurcation lesions (8.6% v 5.6%; $P = 0.02$) and in-stent restenotic lesions (7.9% v 2%; $P < 0.01$) (Box 4). Conversely, in patients who presented with ST-elevation myocardial infarction (STEMI) and cardiogenic shock, more were treated with BMSs than DESs (23.3% v 17.5%; $P = 0.01$ and 1.4% v 0.9%; $P = 0.22$, respectively). There was no significant difference in stent preference in patients presenting with non-ST-elevation acute coronary syndromes.

The percentages of PCIs in which DESs were used in accordance with Department of Human Services criteria is shown in Box 5. DES use ranged from a high of 75.6% for in-stent restenosis down to 52.0% for chronic total occlusions. The likelihood of receiving a DES increased with the number of criteria satisfied (Box 6), from an RR of 1.34 (95% CI, 1.14–1.58) with one criterion present to a RR of 10.41 (95% CI, 6.13–17.5) when three or more criteria were present.

DISCUSSION

In 66.2% of PCIs in this large, contemporary cohort study in the Australian public health care system, patients were eligible for DES use according to Department of Human Services guidelines, and in 45.3% of PCIs, they actually received DESs. In both instances, the requirement for DESs exceeded the 30%–40% for which the Department of Human Services provides funding. In accordance with Department of Human Services guidelines, DESs were predominantly implanted in PCIs involving patients at high risk of restenosis (87.7%), and were more frequently used in patients with diabetes, small vessels (⩽ 2.5 mm), and complex lesions (long segments of disease, bifurcation and ostial lesions, chronic total occlusions and in-stent restenosis). However, in 39.9% of PCIs involving patients who met criteria for DES implantation, a BMS was used.

The uptake of DESs by the interventional cardiology community is not uniform. In the United States, 17 266 PCIs were performed in Veteran Health Administration medical centres from 2002 to 2004, with DES use reported in 52% of cases.[11] On the other hand, a German registry of 3579 interventions at 102 centres reported less than 10% DES use between April 2002 and December 2003.[12] In Australia, DES use in public hospitals varies considerably between states. There are very high rates of DES use (about 90%) in Western Australia, compared with about 60% in South Australia and 50% in New South Wales, where rates in some hospitals were less than 10% (J Rankin, Interventional Cardiologist, Royal Perth Hospital, Perth, WA; D P Chew, Interventional Cardiologist, Flinders Medical Centre, Bedford Park, SA; and D M Muller, Interventional Cardiologist, Director of Cardiac Catheterisation Laboratory,

St Vincent's Hospital, Darlinghurst, NSW; personal communications, March 2006). A recent preliminary report found DES use in Victorian private hospitals exceeded 94% — about twice that of Victorian public hospitals.[13]

The rationale for selective use of DESs is twofold. Firstly, the greatest clinical benefit of DESs is expected for patients at the highest risk of restenosis. A number of clinical and angiographic features are known to increase the risk of restenosis after bare-metal stenting.[14-21] Lesion-related factors are described above. The major patient-related factor is diabetes mellitus, which doubles the risk of in-stent restenosis.[20,21] DESs have been shown to be safe and effective in each of these subgroups.[14,16-18,22-25] A recent study showed the strategy of selective DES use in patients with high-risk features (including diabetes, left ventricular ejection fraction < 35%, lesions in the left anterior descending artery and left main stem artery, saphenous vein grafts, chronic total occlusions, ostial or bifurcation lesions) was associated with a significant decrease in major adverse cardiac events, defined as a composite of death, myocardial infarction and target vessel revascularisation (hazard ratio [HR], 0.45; 95% CI, 0.29–0.72), whereas no difference was observed in patients without high-risk features (HR, 0.95; 95% CI, 0.40–2.28).[26]

Secondly, unrestricted DES use is not economically viable under the public health system. A recent cost-effectiveness analysis in the US suggested the sirolimus-eluting stent would be a cost effective treatment strategy when the rate of restenosis exceeds 18.5%.[27] However, not all patients undergoing PCI are at high risk of restenosis. A recent study of 5239 patients undergoing PCI identified factors (eg, native vessels, de novo lesions, reference diameter > 3.5 mm, lesion length < 5 mm, absence of diabetes and non-ostial lesions) which predicted a low (4%–10%) risk of repeat revascularisation at 9 months.[28] Marginal improvement in outcomes from DES use in these low-risk patients is unlikely to be cost-effective, thus providing the economic basis for current Victorian guidelines. A recent Australian study showed that limiting DES use to patients at the highest risk of restenosis might improve the cost-effectiveness of DESs in an Australian model based on randomised trial results.[29]

A significant number of high-risk patients in our study did not receive DESs. There are a number of possible explanations for why patients who had an indication for a DES received a BMS. First, implanting DESs in tortuous and calcified vessels is more difficult than implanting newer generation low-profile BMSs. The operator may choose to use a more deliverable BMS instead of a DES in the event of failure to deliver a DES. Second, prolonged dual antiplatelet therapy including clopidogrel, which is mandatory after DES implantation, may be undesirable in patients awaiting non-cardiac surgery, at high risk of bleeding or unable to comply with prolonged dual antiplatelet therapy. Third, patients with significant comorbidities or poor prognosis may be excluded. Fourth, acute STEMI was initially considered a relative contraindication for DES use by some operators, resulting in more patients with STEMI receiving BMSs despite having high-risk features, such as diabetes. This stemmed from the lack of randomised trial data and the potential risk of stent thrombosis in the local thrombotic environment of the infarction-related lesion. Recent studies have found DESs to be safe in patients with STEMI.[30] Finally, DESs were only funded for 30%–40% of PCIs, and 66.2% of PCIs in this study involved patients with at least one criterion for receiving DESs. Therefore, operators could not use DESs in many appropriate patients without markedly exceeding the allocated budget.

DESs were implanted during some PCIs (16.5%) without an indication (Box 2). In-stent restenosis in the left main and left anterior descending arteries are associated with worse clinical outcome,[31-34] and may explain why DESs were more often implanted in these vessels even though target vessel type was not one of the criteria for DES use in Victorian Department of Human Services guidelines.

Establishing a nationwide registry with long-term outcomes is essential for assessing whether current DES use is appropriate in Australian interventional practice. Follow-up data to 12 months in our cohort will provide efficacy data for cost-effectiveness analysis and for a selective DES implantation policy relevant to the Australian health system.

Our study has several limitations. Firstly, not all Victorian public hospitals were represented, so our findings may not reflect DES use in non-participating hospitals. However, we would anticipate similar results given that these hospitals are also regulated by the 30%–40% reimbursement limit in Victoria. Secondly, the final choice of stent was at the discretion of the interventionalist, and some of the procedural and patient factors precluding the use of DESs may not have been captured. Finally, because quantitative coronary angiography is not performed routinely in Victorian public hospitals, we used stent length and diameter as surrogates for the lesion length and vessel diameter. However, these measures correlate closely in clinical practice.

In summary, we have shown that in Victorian public hospitals, DESs have been used predominantly in patients with risk factors for restenosis, in accordance with current guidelines. However, many patients at high risk of restenosis did not receive DESs, and greater use of DESs in these patients may substantially improve clinical outcomes by reducing restenosis.

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COMPETING INTERESTS

None identified.

AUTHOR DETAILS

Bryan P Yan, FRACP, Interventional Cardiology Fellow[1]
Andrew E Ajani, FRACP, MD, FJFICM, Interventional Cardiologist and Director of Coronary Care Unit,[1] Senior Lecturer[2]
Stephen J Duffy, PhD, FRACP, MRCP, Head, Cardiology General Services[3]
Gishel New, PhD, FRACP, FACC, Director of Cardiology[2,4]
Mark Horrigan, FRACP, Deputy Director of Cardiology, and Director, Cardiac Catheterisation Laboratory[5]
Gregory Szto, FRACP, Interventional Cardiologist[6]
Antony Walton, FRACP, Interventional Cardiologist[3,7]
David Eccleston, MMedSci, FRACP, Interventional Cardiologist[1,7]
Jeffery Lefkovits, FRACP, Interventional Cardiologist[1]
Alexander Black, FRACP, Director of Cardiology[8]
Martin Sebastian, FRACP, Interventional Cardiologist[8]
Angela L Brennan, RN, Registered Nurse[2,3]
Christopher M Reid, DipEd, MSc, PhD, Deputy Director, NHMRC Centre of Clinical Research

Excellence in Therapeutics, Department of Epidemiology and Preventive Medicine[2]
David J Clark, FRACP, Interventional Cardiologist[5]

1 Royal Melbourne Hospital, Melbourne, VIC.
2 Monash University, Melbourne, VIC.
3 Alfred Hospital Heart Centre, Melbourne, VIC.
4 Box Hill Hospital, Melbourne, VIC.
5 Austin Hospital, Melbourne, VIC.
6 Frankston Hospital, Peninsula Health, Frankston, VIC.
7 Western Hospital, Melbourne, VIC.
8 Geelong Hospital, Geelong, VIC.

Correspondence: clarkdavidj@hotmail.com

Melbourne Interventional Group (MIG) investigators: The following investigators and institutions participated in the Melbourne Interventional Group registry: **Alfred Hospital:** S Duffy, J Shaw, A Walton, C Farrington, R Gunaratne, A Broughton, J Federman, C Keighley, A Dart. **Austin Hospital:** D Clark, J Johns, M Horrigan, O Farouque, L Oliver, J Brennan, R Chan, G Proimos, T Dortimer, B Chan, A Tonkin, L Brown, N Campbell, A Sahar, K Charter. **Box Hill Hospital:** G New, L Roberts, H Liew, M Rowe, G Proimos, N Cheong, C Goods. **Frankston Hospital:** R Lew, G Szto, R Templin. **Geelong Hospital**: A Black, M Sebastian, T Yip, L Ponnuthrai, M Rahmen, J Dyson, T Duplessis. **Monash University**: H Krum, C Reid, A Brennan, A Meehan, P Loane, L Curran and F Groen. **Peninsula Private Hospital:** G Szto, V O'Shea. **Royal Melbourne Hospital:** A Ajani, R Warren, D Eccleston, J Lefkovits, B Yan, P Roy, S Shetty. **Western Hospital:** Y-L Lim, D Eccleston, A Walton.

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