Percutaneous coronary angioplasty in a district general hospital: safe and effective – the Bournemouth model

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Recent studies have suggested that the safety, efficacy and feasibility of percutaneous coronary intervention (PCI) in hospitals without on-site surgical cover is equivalent to those with these facilities. In addition, recent UK figures suggest that PCI growth is in the region of 15% per year with a corresponding fall in coronary artery bypass grafts (CABGs) hence the ratio of PCI to CABG is increasing. In the UK 35% of PCI centres are without on-site surgical cover, however, these centres represent only 18% of total PCI procedures. The Dorset Heart Centre opened in April 2005 the nearest surgical centre being approximately 28 miles in distance. In addition to elective PCI, our centre provides a 9-to-5 Monday-to-Friday primary and rescue PCI service for the Dorset area.

We compared the safety and efficacy of our newly opened non-surgical PCI centre with outcomes predicted using the North West Quality Improvement Programme (NWQIP) multi-variate prediction model to assess the risk of major adverse cardiac and cerebral events (MACCE) in patients undergoing PCI. Between opening and August 2006 we performed 1,454 PCIs. Our overall success rate was 1,363 (94%). Using the NWQIP multi-variate prediction model, the calculated MACCE estimate rate was 2.05%. The actual MACCE rate was 0.55%. We conclude that at our relatively new non-surgical centre we are able to provide an effective and high-volume PCI service to the Dorset region with MACCE rates below that expected for our patient population.

Introduction

Over the last 15 years there has been an almost exponential growth in the percutaneous coronary intervention (PCI) rate in the UK from less than 10,000 procedures in 1991 to over 70,000 in 2005 (British Cardiovascular Intervention Society [BCIS] audit data 2005). The National Service Framework (NSF) for Cardiology (http://www.csp.org.uk/uploads/documents/ebb_cr.pdf) has recommended revascularisation rates of 1,500 per million of population with either cardiac surgery or PCI as the mode of revascularisation. During the same time period the rate of coronary artery bypass graft (CABG) has remained relatively static with the ratio of PCI to CABG increasing from 1.3 in 2000 to 3.1 in 2005. In the UK, 35% of PCI centres do not have on-site surgical cover, however, these centres account for less than 20% of total PCIs. In addition, there is growing evidence for the benefit of primary PCI in the setting of acute ST segment elevation myocardial infarction (STEMI)[1-6] and a move towards day-case elective PCI. With these additional pressures it is anticipated that there will be a need for expansion of PCI services in the UK. Historically, Dorset has been under served in terms of revascularisation for both CABG and more so for PCI with poor access to both elective and non-elective PCI. The Dorset Heart Centre was set up to address these issues and to dramatically improve PCI revascularisation rates in line with the NSF guidelines.

Several registries and studies have suggested that PCI in non-surgical centres with off-site surgical cover may provide a safe alternative to the traditional

model of PCI with on-site cover.[7-11] In the recent Primary Angioplasty in Acute Myocardial Infarction at Hospitals with No Surgery On-Site (PAMI-No SOS) study,[12] which evaluated the outcomes of primary percutaneous transluminal coronary angioplasty (PTCA) in patients with high-risk acute myocardial infarction that presented to hospitals without cardiac surgery, those subjects who underwent on-site primary angioplasty had similar 30-day outcomes and more rapid reperfusion than those transferred to surgical centres. This study concluded that primary angioplasty in high-risk acute myocardial infarction patients at hospitals with no on-site surgical cover is safe, effective, and faster than angioplasty after transfer to a surgical facility. One registry in France of over 50,000 PTCA patients reported no differences in the outcomes of centres with and without cardiac surgery.[13] It must be noted, however, that not all centres with off-site surgical cover obtain such positive results, for example, a study by Wennberg *et al.*,[14] performed in 178 hospitals in the USA showed a significantly higher mortality in PCI patients compared with CABG in low-volume PCI centres (<50 patients per year). In view of this it is essential that PCI centres have a stringent audit and review process to ensure positive results. Moreover, the time to reperfusion is essential to outcomes following acute myocardial infarction, De Luca *et al.* reported an odds ratio of 1.087 in the risk of discharge ejection fraction <30% and 1.075 for the risk of one-year mortality for each 30-minute delay to balloon inflation for primary angioplasty after adjusting for confounding factors.[15] These data provide further argument for those in favour of PCI with off-site cover as pain to balloon times are likely to be significantly reduced.

Our non-surgical PCI centre at the Royal Bournemouth Hospital was opened in April 2005, the nearest surgical centre being approximately 28 miles in distance. In addition to elective PCI, our centre provides a 9-to-5 Monday-to-Friday primary and rescue PCI service for the Dorset area, and employs three full-time interventional cardiologists covering three catheterisation labs. In addition to balloon angioplasty, our centre also has facility for rotational atherectomy, laser atherectomy, pressure wire studies, and intravascular ultrasound (IVUS) with virtual histology.

BCIS approval for our centre was sought in March of 2005, with a subsequent BCIS visit in May of the same year with full approval given at that stage. In addition, full network approval was given for development of the unit including the local primary care trust (PCT), Foundation Trust and Southampton University Hospitals Trust. Prior to commencement, full action plans were agreed for off-site surgical cover for both urgent and emergency transfer from both Southampton University Hospital and Guy's Nuffield Hospital, London, and we have the capability of transferring images to Southampton for surgical colleagues to review. In addition, a consultant cardiothoracic surgeon attends a multi-disciplinary angiogram review session every two weeks to discuss potential surgical cases. Every patient is made aware of the potential need for emergency surgery prior to the procedure and this is clearly documented on the consent form. We conform to BCIS regulations for out-of-hours cover by having an interventional cardiologist available for call back for PCI up to six hours after an intervention Monday to Friday.

Aim

The aim of this study was to investigate the efficacy and safety of our newly opened PCI centre by comparing our in-hospital major adverse cardiac and cerebral events (MACCE) rates with that estimated using a well-established risk-scoring system for PCI in the UK.

Methods

Data were prospectively collected by our lead cardiac physiologist with the aid of a part-time data entry clerk on all cases from the opening of our PCI centre in April 2005 until August 2006. All patient details were recorded using an Excel® database, in addition to procedure success rates and in-patient MACCE rates. Cases included a mix of elective, emergency, primary and rescue PCI. PCI success was defined as a successful dilatation to a residual stenosis <50%, with no evidence of a Q-wave or the need for emergency surgery. We used the North West Quality Improvement Programme in Cardiac Investigations (NWQIP) scoring system to calculate our estimated MACCE rates.[16] This scoring system uses a multi-variable linear-regression model to calculate MACCE rates based on seven factors (**table 1**): patient age, sex, presence of cerebrovascular disease, cardiogenic shock, urgency of procedure, left main stem lesions stenting and graft lesions stenting. We then calculated our actual MACCE rates from collected data for comparison.

Table 1. Factors included in the North West Quality Improvement Programme in Cardiac Investigations (NWQIP) multi-variate regression model

Variable	%
Age 70–79	34.0
Age 80+	14.8
Female	30.8
Cerebrovascular disease	4.1
Shock	0.8
Urgent	50.1
Emergency	6.3
Left main stem	5.4
Grafts	3.9

Results

Over the initial 17-month period we performed 1,454 PCIs of which 768 (52.8%) were for acute coronary syndromes (ACS), 27 (2%) were primary for STEMI, 19 (1.3%) rescue for failed thrombolysis, 436 (30%) were multi-vessel, 49 (3.4%) left main stem lesions (17 protected), 48 (3.3%) used IVUS, 60 (4.1%) included pressure wire studies, 9 (0.6%) rotational atherectomy, and 5 (0.3%) atheroma removal device. Our overall success rate was 1,363 (94%). Total stent use was 89.7% and drug eluting stent use was 53.9%. All patients were pre-loaded with at least 300 mg of clopidogrel.

Using the NWQIP multi-variate prediction model, the calculated MACCE estimate rate was 2.05% based on our cohort of patients. The actual MACCE rate was 0.55%, which consisted of five deaths, one Q-wave myocardial infarction, one non-Q-wave myocardial infarction, and one emergency CABG referral. No patient suffered a cerebrovascular event as a result of the procedure. This represents a 73% lower rate than that estimated for our population.

Discussion

This paper raises several important discussion points. First, we stress the increasing pressures on PCI services in the UK. With rapidly increasing PCI numbers and limited expansion in surgical centres the need for non-surgical PCI centres will continue to increase. Second, increasingly complex PCI procedures may lead to a 'clogging' of tertiary/surgical centre PCI sessions and hence reduce the numbers of routine angioplasty in such areas. Centres with off-site surgical cover have been proven to be effective and safe in several registries and studies. In addition, the reduced time to balloon inflation for primary PCI, which is likely to occur after deleting the need for transfer to a regional centre, may improve both short- and long-term prognosis.

Our data use a recently published multi-variable regression model to compare estimated with actual MACCE rates following PCI in our non-surgical centre. This model was created and validated using a UK population and is therefore likely to represent our own population well. The Dorset Heart Centre's results indicate that our actual MACCE rates are significantly lower than those estimated for the case mix despite a relatively high-risk population. This clearly supports the argument that PCI can be performed safely with low event rates in a non-surgical centre. The explanation for our results is likely to be multi-factorial. First, we have fashioned close links with our regional ambulance services in which paramedics have direct telephone access to our cardiac catheterisation lab for discussion of cases suitable for primary PCI. This allows early transfer to the lab with reduced pain to balloon times and hence likely improved outcomes. Second, our PCI service is high volume with an average of 500 PCIs per consultant per year, thus offering highly experienced operators. Third, all procedures are performed in our dedicated catheterisation labs with well-trained dedicated catheter-lab staff and radiographers with the majority of discharges being nurse led. These factors allow excellence in our provision of service, which has been demonstrated in our department gaining the *Hospital Doctor 2006 Team of the Year* award.

Recently, the BCIS has issued a statement on its website (http://www.bcis.org.uk) that supports the development of PCI in non-surgical centres providing that certain recommendations are adhered to, including that centres should perform a minimum of 200 cases per annum and have robust plans to increase activity to a minimum of 400 cases per annum. In addition, the recommended minimum numbers per operator are 75 per year for an independent operator and 125 per year for a teacher. Results in low-volume centres may be less favourable and stringent audit of outcomes is essential for clinical governance.

Our 9-to-5 PCI service is the initial phase of our unit development. Future aims for the department include increasing our consultant workforce, extending our primary PCI to offer service for our neighbouring hospital (Poole district general hospital) and talks are in progress over a 24/7 service for Dorset and some areas of Wiltshire.

Limitations

We acknowledge that there are several limitations to our report. We only present data on in-hospital MACCE rates, which may confound our actual event rates, however, all patients were stable at the time of discharge. In addition, we do not present data on minor complications, however, again these were low and were not included in the original NWQIP model. It may be hypothesised that our population may be a healthier cohort than assessed in the Northwest of England and hence not fitting the NWQIP regression model, however, Bournemouth has a wide range of ages and social class likely to be similar to the Northwest.

Conclusion

At our relatively new non-surgical centre we are able to provide an effective and high-volume PCI service to the Dorset region with MACCE rates below that expected for our patient population. Our low MACCE rates likely represent our experienced staff and consultant-run service, and we speculate that with the current rate of increase in PCI and falling CABG rates our unit will provide a model for other non-surgical centres in the UK

Conflict of interest

None declared.

Editors' note

An editorial 'Delivering PCI in the UK – need for strategic thinking and a quality agenda' by Dr Mark de Belder is published on pages 227–9.

Key messages

- There has been rapid growth in the percutaneous coronary intervention (PCI) rate in the UK from less than 10,000 procedures in 1991 to over 70,000 in 2005
- Several registries and studies have suggested that PCI in non-surgical centres with off-site surgical cover may provide a safe alternative to the traditional model of PCI with on-site cover
- With rapidly increasing PCI numbers and limited expansion in surgical centres the need for non-surgical PCI centres will continue to increase
- Our non-surgical PCI centre at the Royal Bournemouth Hospital was opened in April 2005, the nearest surgical centre being approximately 28 miles in distance
- Our data use a recently published multi-variable regression model to compare estimated with actual major adverse cardiac and cerebral event (MACCE) rates following PCI in our non-surgical centre: the calculated MACCE estimate rate was 2.05%, the actual MACCE rate was 0.55%
- Our unit could provide a model for other non-surgical centres in the UK

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