Chapter 5

High-risk coronary intervention: a selective literature review of high-risk subsets

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Introduction

The use of percutaneous coronary intervention (PCI) to treat ischaemic coronary artery disease (CAD) has expanded dramatically over the past 25 years. From its incipience as an alternative to coronary bypass surgery in selected patients with single-vessel disease, PCI has evolved into the preferred revascularization strategy in the 900,000 patients who undergo this procedure annually in the USA. The safety and durability of PCI have improved dramatically since 1979 [1], due to continual technological improvements (e.g. drug-stents, distal protection devices), refinements in peri-procedural adjunctive pharmacology (e.g. glycoprotein IIb–IIIa [GP IIb–IIIa] inhibitors, alternative thrombin inhibitors), and a better understanding of early and late outcomes associated with low- and high-risk patients.

This review will focus on the pivotal literature that describes the clinical outcomes of patients undergoing "high-risk" coronary intervention. We begin with a description of the percutaneous transluminal coronary angioplasty (PTCA) of the National Heart, Lung, and Blood Institute (NHLBI) Registry (Paper no. 1), which was critical for the evaluation of the success rates associated with balloon angioplasty in high-risk patients. Detre and her colleagues at the University of Pittsburgh have documented the outcomes associated with PCI for the past 25 years in the NHLBI PTCA Registry [2], coronary bypass surgery or balloon angioplasty in patients with multivessel disease BARI (Bypass Angioplasty Revascularization Investigation) trial [3], new device angioplasty (New Approaches to Coronary Intervention, NACI, Registry) [4], and the ongoing DYNAMIC Registries [5]. Their work has allowed us to document temporal improvement in outcomes and practice strategies [6].

A number of "high-risk" subsets have been identified that predict both early complications and late clinical outcome. In the second manuscript of this series (Paper no. 2), Kip and colleagues characterize the long-term clinical outcome of patients with diabetes mellitus who underwent successful balloon angioplasty in the NHLBI PTCA Registry [7]. From this series, we find a sobering glimpse into the late mortality rates associated with the extensive atherosclerotic disease in diabetic patients. Improving the late-term prognosis in diabetic patients has been a major focus of recent therapies, but it is clear that interventional approaches need to be coupled with aggressive risk factor modification in diabetic patients. Ongoing trials, such as the FREEDOM trial, will address the benefit of surgical revascularization in diabetic patients with multivessel CAD. The end-organ effects of diabetes likely contributes to the recently identified risk of mild-to-moderate renal insufficiency on late procedural outcomes that is described by Best and colleagues at the Mayo Clinic (Paper no. 3). Using a more sophisticated index of renal function, creatinine clearance is related to late clinical events. Even a mild degree of renal dysfunction is associated with a heightened risk for an adverse event, with an incremental worse outcomes with increasing degrees of renal insufficiency [8].

Three other risk groups were identified in the early PTCA series. Cowley and colleagues describe the higher in-hospital mortality and complication rates noted in women compared with

men when balloon angioplasty was the only option (Paper no. 4). It is likely that the arterial barotrauma occurring during balloon inflation contributed to this higher complication rate in women [9]. With improvements in equipment design and the frequent use of coronary stents, clinical outcomes of women undergoing PCI has improved substantially, now considered equally effective in men and women. Another potential high-risk group includes patients with reduced left ventricular function. Holmes and colleagues describe the outcome of patients with reduced left ventricular function treated with balloon angioplasty (Paper no. 5). Somewhat surprisingly, favourable outcomes were found in carefully selected patients with reduced left ventricular function [10]. The final clinical "high-risk" groups included in this series are patients who present with acute myocardial infarction that is complicated by cardiogenic shock. The historical mortality rate of patients with cardiogenic shock approached 80% in medically treated patients. Hochman and colleagues (Paper no. 6) found a modest reduction in the mortality rate in these patients using an early aggressive approach to revascularization, particularly in younger patients (<75 years). As a result, revascularization therapy is now preferred to thrombolytic therapy in patients who present with cardiogenic shock.

A number of angiographical risk factors that predict an unfavourable outcome after PCI have also been identified and are useful for the triage of patients to medical therapy, PCI, or coronary artery bypass graft (CABG) [11]. In a multicenter series of patients undergoing multivessel balloon angioplasty, Ellis and colleagues validate the empiric observations of the American College of Cardiology – American Heart Association PTCA Guidelines Writing Group (Paper no. 7). These observations showed that the angiographical criteria were important predictors of procedural outcome [12]. Three additional high-risk subsets that portend a great risk for failure or complications after PCI are then reviewed. Platko and colleagues describe the outcome of patients undergoing balloon angioplasty of saphenous vein stenoses (Paper no. 8) and identify the importance of saphenous vein graft age and its effect on the occurrence of distal embolization. Holmes and colleagues (Paper no. 9) describe the early NHLBI experience with total occlusions, setting the stage for a variety of innovative tools that are used to cross total coronary occlusions [13]. Despite these advances, total coronary occlusion remains the major reason for referral to coronary artery bypass surgery rather than recurrent intervention. In the final paper in this series, George and associates report the initial experience with "kissing balloon" inflation for bifurcation lesions (Paper no. 10). Although stand-alone balloon angioplasty is rarely performed for bifurcation lesions, "kissing balloon" inflation strategy is a critical component of all PCI bifurcation strategies [14].

In aggregate, coronary interventional has advanced dramatically over the past 25 years. Some initial risk factors are no longer important, whereas others, such as diabetes mellitus, total coronary occlusions, and complex saphenous vein graft disease remain important clinical challenges.

Title 1

Percutaneous transluminal coronary angioplasty in 1985–1986 and 1977–1981: the National Heart, Lung, and Blood Institute Registry

Author

Detre K, Holubkov R, Kelsey S, *et al*.

Reference

N Engl J Med 1988; **318**: 265

Abstract

In August 1985, the Percutaneous Transluminal Coronary Angioplasty Registry of the National Heart, Lung, and Blood Institute reopened at its previous sites to document changes in angioplasty strategy and outcome over time. The new registry entered 1802 consecutive patients who had not had a myocardial infarction in the 10 days before angioplasty. Patient selection, technical outcome, and short-term major complications were compared with those of the 1977 to 1981 registry cohort. The new-registry patients were older and had a significantly higher proportion of multivessel disease (53% versus 25%, $p < 0.001$), poor left ventricular function (19% versus 8%, $p < 0.001$), previous myocardial infarction (37% versus 21%, $p < 0.001$), and previous coronary bypass surgery (13% versus 9%, $p < 0.01$). The new-registry cohort also had more complex coronary lesions, and angioplasty attempts in these patients involved more multivessel procedures. Despite these differences, the in-hospital outcome in the new cohort was better. Angiographic success rates according to lesion increased from 67% to 88% ($p < 0.001$), and overall success rates (measured as a reduction of at least 20% in all lesions attempted, without death, myocardial infarction, or coronary bypass surgery) increased from 61% to 78% ($p < 0.001$). In-hospital mortality for the new cohort was 1%, and the nonfatal myocardial infarction rate was 4.3%. Both rates are similar to those for the old registry.

Summary

The National Heart, Lung, and Blood Institute (NHLBI) Registry demonstrated that there were substantial improvements in operator experience and equipment design over the first decade of balloon angioplasty. More complex patients were treated, and procedural success rates increased from 61% to 78%. Despite more complex patients, overall complication rates were unchanged over the study period.

Citation Count 644

Key message

Investigators in the registry have performed angioplasty since before 1980 and thus rank as the most experienced. Certainly, with less experienced operators one would initially expect a less complex angioplasty strategy as well as lower success rates. However, some studies have suggested that improved technique have allowed recent beginners to learn faster.

Why it's important

In the early days of balloon angioplasty, improvements in outcomes were generally documented using single-centre registries and operator anecdotes about their personal experience. The NHBLI Percutaneous Transluminal Coronary Angioplasty (PTCA) Registry was the first to centralize the data collection mechanism, and provide independent and objective assessments of procedural outcome.

Strengths

The standardized data collection forms and definitions used to characterize baseline clinical characteristics and procedural outcomes became the cornerstone for the evaluation of new devices used to treat more complex patient subsets.

Weaknesses

With the rapid evolution of interventional technique and devices, the major limitation of the Registry was that the information was nearly outdated as soon as it is published, and many subtle changes in technique that affect outcome were not captured.

Relevance

In the 25 years following the introduction of balloon angioplasty by Gruentzig and his colleagues, first in Zurich and later in Atlanta [1], the technique of non-surgical coronary artery revascularization has evolved so dramatically that vestiges of "plain 'ole balloon angioplasty" or POBA are barely recognizable. In the early days, a dedicated group of investigators formed the NHLBI PTCA Registry to provide objective analysis of the outcomes associated with balloon angioplasty. A 61% procedural success rate seems unacceptable using contemporary standards, but in the 1977–1981 PTCA Registry, it was viewed as a remarkable success. The subsequent comparisons of the 1985–1986 PTCA Registry results with the early series demonstrated that progress had been made, and more complex patients could be safely treated. This cited Registry also served as the backbone for the objective assessment of outcomes after balloon angioplasty and provided detailed information about early and late (up to 9 years) outcomes after PCI. With the introduction of new devices, the PTCA Registry gave rise to the New Approaches to Coronary Intervention (NACI) Registry that evaluated outcomes with directional, rotation, and extraction atherectomy, excimer laser angioplasty, and stent placement using the Palmaz–Schatz and Gianturco–Roubin stents [4]. Current practice is now captured using a series of time-limited DYNAMIC Registries that document the rapidly changing trends in stent use [5]. These registries series have been invaluable for tracking changes in outcomes in patients with complex lesion subsets [6,15].

Title 2

Coronary angioplasty in diabetic patients: the National Heart, Lung, and Blood Institute Percutaneous Transluminal Coronary Angioplasty Registry

Author

Kip KE, Faxon DP, Detre KM, Yeh W, Kelsey SF, Currier JW

Reference

Circulation 1996; **94**: 1818–1825

Abstract

Patients with diabetes mellitus are at increased risk for cardiovascular disease. Data on baseline clinical and angiographic characteristics and short- and long-term outcomes of 281 diabetic and 1833 nondiabetic PTCA patients in the multicenter National Heart, Lung, and Blood Institute 1985–1986 PTCA Registry were analyzed. Diabetic patients were older, were more likely to be female, and had more co-morbid baseline conditions, triple vessel disease, and atherosclerotic lesions. Angiographic success and completeness of revascularization did not differ significantly, yet diabetic patients experienced more in-hospital death (women) and nonfatal myocardial infarction. Nine-year mortality was twice as high in diabetic patients (35.9% versus 17.9%). Similarly, 9-year rates of nonfatal myocardial infarction (29.0% versus 18.5%), bypass surgery (36.7% versus 27.4%), and repeat PTCA (43.7% versus 36.5%) were higher in diabetics than in nondiabetics. In multivariate analysis, diabetes remained a significant predictor of decreased 9-year survival and other untoward events.

Summary

Compared with non-diabetic percutaneous transluminal coronary angioplasty (PTCA) patients, diabetic patients have more extensive and diffuse atherosclerotic disease. Despite similar probability of angiographical success, diabetic patients are more likely to suffer in-hospital death (women) and nonfatal myocardial infarction. Long-term survival and freedom from myocardial infarction and coronary revascularization are also reduced in diabetic PTCA patients.

Citation Count 165

Key message

A diabetic patients with single-vessel disease has the same 9-year mortality rate as a non-diabetic patient with three-vessel coronary artery disease.

Why it's important

The results of this long-term outcome study in diabetic patients demonstrated that the prognosis of diabetic patients is much worse than patients who do not have diabetes mellitus.

Strengths

Standardized data collection case reported forms and planned long-term follow-up render this registry unique amongst registries and provide a unique opportunity to characterize the natural history of patients successfully treated with balloon angioplasty.

Weaknesses

This study was performed prior to the availability of a number of systemic therapies for diabetic patients that would favorably affect their long-term prognosis, including better agents for glycaemic control, lipid-lowering therapy with statins, angiotensin-converting enzyme inhibitors, and beta-blockers. This study was also performed before the availability of coronary stents, and now drug-eluting stents, but these therapies are not useful in preventing late mortality in patients with coronary artery disease.

Relevance

Controversy still exists about the appropriate revascularization strategy for diabetic patients with multivessel coronary artery disease [3]. This registry report delineates the challenges in the diabetic patient – long-term prognosis relates more to the underlying atherosclerotic disease than it does to the flow-limiting stenosis [16]. The protective effect of the left internal mammary artery (LIMA) graft to the left anterior descending, particularly in insulin-requiring diabetes, may relate to the ability to maintain perfusion of the anterior wall via the LIMA in the event of more proximal plaque rupture in the diabetic patient. Ongoing evaluation in the ongoing BARI (Bypass Angioplasty Revascularization Investigation) 2D trial in diabetic patients will evaluate late term outcomes in patients assigned to insulin-providing or insulin-sensitizing agents or to revascularization therapy (percutaneous or surgical) or aggressive medical therapy. The FREEDOM trial is also planned to evaluate the outcome of diabetic patients with multivessel disease to surgical or drug-eluting stents on the background of aggressive medical therapy.

Title 3

The impact of renal insufficiency on clinical outcomes in patients undergoing percutaneous coronary interventions

Author

Best PJ, Lennon R, Ting HH, *et al*.

Reference

J Am Coll Cardiol 2002; **39**: 1113–1119

Abstract

This study sought to determine the effect of varying degrees of renal insufficiency on death, and cardiac events during and after a percutaneous coronary intervention (PCI). Cardiac mortality and all-cause mortality were determined for 5327 patients undergoing PCI from January 1, 1994, to August 31, 1999, at the Mayo Clinic, based on the estimated creatinine clearance or whether the patient was on dialysis. In-hospital mortality was significantly associated with renal insufficiency ($p = 0.001$). Even after successful PCI, one-year mortality was 1.5% when the creatinine clearance was >70 ml per minute ($n = 2558$), 3.6% when it was 50 to 69 ml per min ($n = 1458$), 7.8% when it was 30 to 49 ml per minute ($n = 828$) and 18.3% when it was <30 ml per minute ($n = 141$). The 18.3% mortality rate for the group with <30 ml per min creatinine clearance was similar to the 19.9% mortality rate in patients on dialysis ($n = 46$). The mortality risk was largely independent of all other factors.

Summary

Renal insufficiency is a strong predictor of death and subsequent cardiac events in a dose-dependent fashion during and after percutaneous coronary intervention (PCI). Patients with renal insufficiency have more baseline cardiovascular risk factors, but renal insufficiency is associated with an increased risk of death and other adverse cardiovascular events, independent of all other measured variables.

Citation Count 83

Key message

The principal finding of this study is that renal dysfunction significantly increases the risk of death and cardiac death during and after PCI in a dose-dependent manner. Even mild renal insufficiency (creatinine clearance 70 ml/min) has an important association with 1-year mortality (relative risk 1.46) and is nearly as predictive as diabetes mellitus.

Why it's important

The contribution of mild degrees of renal insufficiency on late mortality in patients undergoing coronary intervention is an important clinical finding, and may serve as an important marker of vascular disease. Creatinine clearance rather than use of the baseline serum creatinine should be determined, particular in low-weighted women.

Strengths

This is a large registry from the Mayo Clinic that has routine surveillance to assess late term mortality rates.

Weaknesses

The limitation for this study was that therapies that may change the outcomes associated with renal insufficiency were not well characterized and there was limited insight into the precise mechanism by which renal insufficiency affected prognosis.

Relevance

It has been recognized since the early 1990s that patients with end-stage renal disease and those on chronic dialysis are at increased risk of morbidity and mortality after percutaneous intervention [17–24]. A more recent report has described the outcomes of patients with mild degrees of renal insufficiency [25], and a report from the DYNAMIC Registry has also suggested that the baseline serum creatinine is an important predictor of late clinical events [26]. The significance of the current study is that the risk of late mortality is related to incremental reductions in creatinine clearance, beginning with mild degrees of renal dysfunction. This may also have important implications for patients who develop bleeding complications after intervention.

Title 4

Sex differences in early and long-term results of coronary angioplasty in the NHLBI PTCA Registry

Author

Cowley MJ, Mullin SM, Kelsey SF, *et al*.

Reference

Circulation 1985; **71**: 90–97

Abstract

To assess whether gender influenced the outcome of percutaneous transluminal coronary angioplasty (PTCA), early outcomes were compared in 705 women and 2374 men enrolled in the NHLBI PTCA Registry. Women were older ($p < 0.01$) and had more unstable angina ($p < 0.01$), and class 3 or 4 angina ($p < 0.01$). Men had more multivessel disease ($p < 0.01$), prior bypass surgery ($p < 0.01$), and abnormal left ventricular function ($p < 0.05$). Women had a lower angiographic success rate (60.3% versus 66.2% in men; $p < 0.01$) and had a lower clinical success rate (56.6% versus 62.2% in men; $p < 0.01$). More women had complications (27.2% versus 19.4% in men; $p < 0.01$), but overall frequency of major complications (death, myocardial infarction, emergency surgery) was not different (9.8% versus 9.3% in men). Women had a higher incidence of coronary dissection ($p < 0.05$) and higher in-hospital mortality (1.8% versus 0.7% in men; $p < 0.01$). PTCA-related mortality was nearly six times higher in women (1.7% versus 0.3% in men; $p < 0.001$) and mortality with emergency surgery was more than five times higher (17.4% versus 3.2% in men; $p < 0.001$). Multivariate analysis indicated that female gender was an independent predictor for lower success ($p < 0.05$) and early mortality ($p < 0.05$) and was the only baseline predictor for PTCA-related mortality.

Summary

In the 1977–1978 percutaneous transluminal coronary angioplasty (PTCA) Registry, women fared far worse than men after balloon angioplasty, with a six times higher PTCA-related mortality rate and a five times higher need for emergency coronary artery bypass surgery. There were differences in co-morbidities in men and women, but gender was the only independent predictor for in-hospital mortality.

Citation Count 156

Key message

PTCA in women is associated with a significantly lower success rate and a higher in-hospital mortality rate than in men. However, during follow-up after successful PTCA, women have a comparable symptomatic improvement, a lower incidence of additional revascularization procedures and restenosis, and improved survival compared with men.

Why it's important

This 1977–1978 National Heart, Lung, and Blood Institute (NHLBI) Registry series was an extremely useful glimpse into the independently adjudicated early and late outcomes at multiple clinical sites proficient in PTCA. The Registry laid the foundation for the documentation of improved outcomes over time with advances in equipment design, operator experience, and with the availability of new devices.

Strengths

This NHLBI Registry provided data collection using standardized definitions for baseline and procedural variables, and late clinical outcomes.

Weaknesses

With rapid evolution of PTCA methods, the results of this Registry were outdated nearly as quickly as they were published. Nevertheless, documentation of the initial experience has proven invaluable to assess improvements over time.

Relevance

The 1985–1986 NHLBI PTCA [27] and the Northern New England Cardiovascular Disease Study Group [28] also reported a higher in-hospital mortality and complication rates in women than men, due to a higher incidence of procedural complications, whereas the European experience reported similar outcomes for men and women [29]. Advances in equipment design and operator experience in the 1990s [30], coupled with the introduction of coronary stents, substantially improved the outcomes of coronary intervention in women [31–36]. It is now felt that men and women have comparable outcomes after percutaneous coronary intervention (PCI).

Title 5

Long-term outcome of patients with depressed left ventricular function undergoing percutaneous transluminal coronary angioplasty: the NHLBI PTCA Registry

Author

Holmes DR, Detre KM, Williams DO, Kent KM, King SB, Yeh W, Steenkiste A

Reference

Circulation 1993; **87** 2002; **39**: 21–29

Abstract

Coronary revascularization with bypass has been shown to improve survival in patients with coronary artery disease and left ventricular dysfunction. The purpose of this investigation was to characterize the outcome of angioplasty in patients with decreased left ventricular function and contrast it with the results in patients with normal left ventricular function. In the 1985–1986 National Heart, Lung, and Blood Institute's percutaneous transluminal coronary angioplasty (PTCA) Registry, of 1802 patients undergoing PTCA, 244 patients (13.5%) had an ejection fraction of ⩽45% (mean, 39.6). These patients had a higher incidence of prior infarction, a longer and worse history of manifestations of coronary disease, and more extensive coronary artery disease than patients with well-preserved function; 88% and 91%, respectively, had successful dilation of at least one lesion (non-significant difference). However, patients with decreased left ventricular function had a decreased frequency of successful dilation of all lesions in which PTCA was attempted (76% versus 84%, $p < 0.01$). There were no statistically significant differences in in-hospital complications – death occurred in 0.8% and 0.7%, nonfatal myocardial infarction occurred in 4.9% and 4.5%, and emergency surgical revascularization was performed in 4.5% and 3.2%, respectively. Patients were followed for a mean of 4.1 years; during this time, patients with decreased left ventricular function had significantly worse survival and combined event-free survival. Despite this, at 4 years, 87% of the patients with a mean ejection fraction of 39.6% remained alive, and 77% were alive and had not experienced infarction or required bypass.

Summary

Percutaneous transluminal coronary angioplasty (PTCA) is effective in selected patients with depressed left ventricular function. Initial outcome and risk–benefit ratio are excellent. Successful dilation of at least one vessel was achieved in 88% of patients with depressed left ventricular function and in 91% of patients with more normal left ventricular function. The former group, however, had a decreased incidence of successful dilation in all lesions in which dilation was attempted (76% vs. 84%, $p < 0.01$). There was no significant difference in in-hospital complications between the two groups. During follow-up, patients with decreased left ventricular function had worse event-free survival, although 77% were alive without infarction or bypass grafting at 4 years.

Citation Count 36

Key message

These multicenter data document the efficacy of PTCA in selected patients with suitable angiographical anatomy but depressed left ventricular function.

Why it's important

This study demonstrated that patients with reduced left ventricular function could safely undergo coronary intervention without an excess of complications.

Strengths

This National Heart, Lung, and Blood Institute (NHLBI) Registry provided data collection using standardized definitions for baseline and procedural variables, and late clinical outcomes.

Weaknesses

Patients with severe (left ventricular ejection fraction < 0.20) were not well characterized in this study.

Relevance

Transient occlusion of the epicardial vessel during percutaneous coronary intervention (PCI) is known to cause transient regional wall motion abnormalities. PCI in patients with reduced left ventricular function has the potential to worsen the heart failure and cause pulmonary oedema. On occasion, in patients with elevated pulmonary capillary wedge pressures, an intra-aortic balloon pump during PCI has proven useful [37]. Although one early report suggested that complications were increased in patients with reduced ventricular function [38], this cited report suggests that patients with reduced left ventricular function can be treated safely with PCI.

Title 6

One-year survival following early revascularization for cardiogenic shock

Author

Hochman JS, Sleeper LA, White HD, *et al*.

Reference

JAMA 2001; **285**: 190–192

Abstract

To assess the effect of early revascularization (ERV) on 1-year survival for patients with acute myocardial infarction (AMI) complicated by cardiogenic shock, the SHOCK (Should We Emergently Revascularize Occluded Coronaries for Cardiogenic Shock) trial, an unblinded, randomized controlled trial was conducted from April 1993 through November 1998. Thirty-six referral centers with angioplasty and cardiac surgery facilities enrolled 302 patients with AMI and cardiogenic shock due to predominant left ventricular failure who met specified clinical and hemodynamic criteria. Patients were randomly assigned to an initial medical stabilization (IMS; $n = 150$) group, which included thrombolysis (63% of patients), intra-aortic balloon counterpulsation (86%), and subsequent revascularization (25%), or to an ERV group ($n = 152$), which mandated revascularization within 6 hours of randomization and included angioplasty (55%) and coronary artery bypass graft surgery (38%). One-year survival was 46.7% for patients in the ERV group compared with 33.6% in the IMS group (absolute difference in survival, 13.2%; 95% confidence interval [CI], 2.2–24.1%; $p < 03$; relative risk for death, 0.72; 95% CI, 0.54–0.95). Of the 10 prespecified subgroup analyses, only age (<75 versus ⩾75 years) interacted significantly ($p < 0.03$) with treatment in that treatment benefit was apparent only for patients younger than 75 years (51.6% survival in ERV group versus 33.3% in IMS group). Eighty-three percent of 1-year survivors (85% of ERV group and 80% of IMS group) were in New York Heart Association class I or II.

Citation Count 74

Key message

Early revascularization (ERV) therapy resulted in a 39% improvement in 1-year survival compared with initial medical stabilization. The absolute benefit of early revascularization therapy for cardiogenic shock saves 132 lives for every 1000 patients treated, and is … is similar to the absolute benefit of coronary artery bypass grafting (CABG) for left main coronary artery disease at 1 year.

Why it's important

The study demonstrated the benefit of an early aggressive strategy in patients with cardiogenic shock who were <75-year old.

Strengths

This randomized, multicentre trial demonstrated a clear benefit of revascularization therapy in younger patients with cardiogenic shock with mortality rates with medical therapy that were similar to prior registries.

Weaknesses

The study enrolled its 300 patients over several years due to challenges with recruitment. It is possible that some of the sickest patients with cardiogenic shock were excluded from the study.

Relevance

Cardiogenic shock (CS) is the leading cause of death for patients hospitalized with acute myocardial infarction (AMI). Although a number of registry reports in the late 1980s and early 1990s suggested that revascularization therapy improved the prognosis compared with medical therapy [39–43], it also appeared that the sickest patients with cardiogenic shock never made it to the catheterization laboratory, and no randomized trials demonstrated the benefit of ERV. The importance of this clinical trial was that patients were assigned to an aggressive medical therapy arm or to revascularization therapy, and clear survival benefits were demonstrated in patients assigned to revascularization therapy. The age restriction of <75-year old may be revised with the recent report from Northern New England Registry. From 1990 to 2000, a total of 310 out of 52,418 patients (0.59%) had percutaneous coronary intervention (PCI) for cardiogenic shock, 24% of whom were elderly (>75 years). Procedural characteristics were similar between the two groups. Independent predictors of mortality for both groups were older age and the absence of collaterals; during the stent era (1997–2000), significant predictors were lack of stent placement and diabetes mellitus. The mortality rate for elderly shock patients undergoing PCI was 46%, which is significantly less than previously reported in randomized clinical trials [44].

Title 7

Coronary morphologic and clinical determinants of procedural outcome with angioplasty for multivessel coronary disease. Implications for patient selection: Multivessel Angioplasty Prognosis Study Group

Author

Ellis SG, Vandormael MG, Cowley MJ, *et al*.

Reference

Circulation 1990; **82**: 1193–1202

Abstract

To assess the likelihood of procedural success in patients with multivessel coronary disease undergoing percutaneous coronary angioplasty, 350 consecutive patients (1100 stenoses) from four clinical sites were evaluated. Eighteen variables characterizing the severity and morphology of each stenosis and 18 patient-related variables were assessed at a core angiographic laboratory and at the clinical sites. Most patients had Canadian Cardiovascular Society class III or IV angina (72%) and two-vessel coronary disease (78%). Left ventricular function was generally well preserved and 1.9 stenoses per patient had attempted percutaneous coronary angioplasty. Procedural success (⩽50% final diameter stenosis in one or more stenoses and no major ischemic complications) was achieved in 290 patients (82.8%), and an additional nine patients (2.6%) had a reduction in diameter stenosis by 20% or more with a final diameter stenosis 51–60% and were without major complications. Major ischemic complications (death, myocardial infarction, or emergency bypass surgery) occurred in 30 patients (8.6%). In-hospital mortality was 1.1%. Stepwise regression analysis determined that a modified American College of Cardiology/American Heart Association Task Force (ACC/AHA) classification of the primary target stenosis (with Type B prospectively divided into Type B1 [one Type B characteristic] and Type B2 [greater than or equal to two Type B characteristics]) and the presence of diabetes mellitus were the only variables independently predictive of procedural outcome (target stenosis modified ACC/AHA score; p less than 0.001 for both success and complications; diabetes mellitus: $p = 0.003$ for success and $p = 0.016$ for complications). Analysis of success and complications on a per stenosis dilated basis showed, for type A stenoses, a 92% success and a 2% complication rate; for Type B1 stenoses, an 84% success and a 4% complication rate; for Type B2 stenoses, a 76% success and a 10% complication rate; and for Type C stenoses, a 61% success and a 21% complication rate. The subdivision into Types B1 and B2 provided significantly more information in this clinically important intermediate risk group than did the standard ACC/AHA scheme. The stenosis characteristics of chronic total occlusion, high grade (80–99% diameter) stenosis, stenosis bend of more than 60 degrees, and excessive tortuosity were particularly predictive of adverse procedural outcome.

Summary

This improved scheme may improve clinical decision making and provide a framework on which to base meaningful subgroup analysis in randomized trials assessing the efficacy of percutaneous coronary angioplasty.

Citation Count

618

Key message

Good short-term results can be obtained with coronary angioplasty performed by experienced operators in patients with multivessel disease in whom the important stenosis has Type A or B1 characteristics. However, when the important stenoses have Type B2 or C characteristics, other forms of therapy should be very strongly considered.

Why it's important

This study prospectively validated the empiric impression of the American College of Cardiology and American Heart Association Percutaneous Transluminal Coronary Angioplasty (ACC/AHA PTCA) Guidelines Committee that suggested that procedure success and complications rates could be estimated from assessing the baseline lesion morphology.

Strengths

This study was one of the first to use an independent core laboratory assessment of procedural outcomes relating to the lesion morphology.

Weaknesses

Despite standardized criteria, there was substantial variability in the identification of adverse lesion characteristics from the angiogram by clinical investigators. Some of the morphological features predicted procedural failure (e.g. total occlusion) whereas others predicted complications (e.g. thrombus, degenerated saphenous vein grafts).

Relevance

In 1988, a joint task force of the ACC and AHA established an empiric classification system for lesion complexity [11]. These risk factors have subsequently been shown to be predictive in a number of single- and multicentre studies using other devices [45], including coronary stents [46]. Although overall success rates have increased and complication rates have lowered [47], the overall effect of lesion morphology on procedural outcomes has persisted in most studies [48–50].

Title 8

Percutaneous transluminal angioplasty of saphenous vein graft stenosis: long-term follow-up

Author

Platko WP, Hollman J, Whitlow PL, Franco I

Reference

J Am Coll Cardiol 1989; **14**: 1645–1650

Abstract

Percutaneous transluminal angioplasty was used to treat 101 patients with saphenous vein bypass graft stenosis at a mean of 50.1 months (range 2 to 196) after coronary artery bypass surgery. The patients presented between March 1981 and April 1987. A total of 107 saphenous vein grafts were dilated at 117 sites. The primary success rate was 91.8%. The incidence of cardiac complications was 7.1%. There were no cardiac complications in 53 patients with grafts implanted less than 36 months before angioplasty (Group 1). The 48 patients with grafts implanted for greater than 36 months (Group 2) had a 12.5% incidence rate of myocardial infarction, a 4% incidence rate of emergent bypass surgery and a 4% incidence rate of death for an overall cardiac complication rate of 14.9% (p less than 0.01). Follow-up was obtained at a mean of 16.8 $\pm$ 13.9 months (range 1 to 54) in 87 patients (97% of successful cases). Repeat coronary angiography was performed in 49 patients and revealed restenosis in 30 patients (61.2%), with no difference in recurrence rates for proximal, mid or distal graft sites. Clinical recurrence (defined as recurrence of symptoms, myocardial infarction, repeat angioplasty, surgery or death) was 33.1% for Group 1 patients and 64.1% for Group 2 patients (p less than 0.01).

Summary

The complication and recurrence rates of saphenous vein graft angioplasty are significantly higher when performed for late (>36 months) vein graft failure. All therapeutic options should be carefully examined before proceeding with angioplasty for saphenous vein graft stenosis in this type of patient.

Citation Count 146

Key message

There is a 6% likelihood of myocardial infarction, 2% likelihood of emergency coronary bypass surgery, and a 2% mortality rate (associated with angioplasty of saphenous vein graft, SVGs) … All of these complications occurred after angioplasty on grafts implanted >36 months after the operation.

Why it's important

This work evaluated graft age and degeneration on the occurrence of procedural outcome after balloon angioplasty.

Strengths

This single-centre series was one of the first to describe the outcomes associated with SVG intervention.

Weaknesses

The major limitation of the study was the failure to characterize the angiographical appearances of the SVG in an effort to identify predictors of risk. The addition of distal protection devices and coronary stents have markedly improved procedural outcomes in these patients.

Relevance

SVG interventions remain a clinical challenge for the interventionalist. This study related the procedural outcome to SVG age, suggesting that older SVGs were more friable and susceptible to complications. Over the years, the prognostic importance of the complications occurring during SVG intervention was further characterized [51–57]. Distal embolization was later associated with substantial morbidity and mortality [58]. A number of distal protection devices have been designed to reduce these complications and have now become integrated in contemporary interventional practice.

Title 9

Angioplasty in total coronary artery occlusion

Author

Holmes DR, Vlietstra RE, Reeder GS, *et al*.

Reference

J Am Coll Cardiol 1984; **3**: 845–849

Abstract

Percutaneous transluminal coronary angioplasty was attempted without streptokinase in 24 patients with total coronary artery occlusion but without acute transmural myocardial infarction. The maximal duration of occlusion was estimated to be 1 week or less in 10 patients, more than 1 to 4 weeks in 6, more than 4 to 12 weeks in 3 and more than 12 weeks in 5. Dilation of the occluded artery was attempted in the left anterior descending coronary artery in 17 patients, in the right coronary artery in 4 and in the circumflex coronary artery in 3. Angioplasty was successful in 13 patients (54%): left anterior descending coronary artery in 59%, right coronary artery in 50% and circumflex coronary artery in 33%. In patients with successful dilation, there was a mean decrease in coronary artery stenosis from 100 to 23%. In the 19 patients whose occlusion was estimated to be of 12 weeks' duration or less, angioplasty was successful in 68%. In the five patients whose occlusion was estimated to be of more than 12 weeks' duration, dilation was not successful in any ($p = 0.006$).

Summary

In selected patients with symptomatic coronary artery disease and recent coronary artery occlusion without associated acute myocardial infarction, percutaneous transluminal coronary angioplasty (PTCA) alone may be effective in restoring patency.

Citation Count

125

Key message

Total occlusion is not by itself a contraindication to coronary angioplasty. Successful dilatation can be performed in approximately two-thirds of selected patients with recent (<12 weeks) total occlusion.

Why it's important

This was one of the earliest reports of the success rates associated with the use of PTCA for total coronary occlusion.

Strengths

This initial single-centre registry report provided important insight into a subset of patients who were deemed unsuitable for coronary angioplasty.

Weaknesses

In the early days of angioplasty, the equipment was much less sophisticated and precluded crossing the total occlusion in many cases.

Relevance

Percutaneous intervention of total coronary occlusions remains of the major challenges. Several early series describe angiographical criteria that were deemed predictors of unlikely success with intervention in total occlusions, including bridging collaterals, flush occlusions, and the presence of a branch vessel arising from the occlusion [13,59–61]. A progressive improvement of the procedural success rates have been achieved, particularly with the use of new hydrophilic coronary guidewires, but total coronary occlusions remain the most frequent cause for referral for coronary artery bypass surgery.

Title 10

Balloon angioplasty of coronary bifurcation lesions: the kissing balloon technique

Author

George BS, Myler RK, Stertzer SH, *et al*.

Reference

Cathet Cardiovasc Diagn 1986; **12**: 124–138

Abstract

Initial experience with the technique of "kissing balloon" angioplasty is described in 52 patients undergoing coronary angioplasty. Guiding catheters employing both the femoral and brachial approach were used in all but two of the coronary angioplasties and, in addition, the bilateral femoral approach was used in the renal and peripheral angioplasties. Initial success was achieved in 51 (98%) patients. Abrupt closure requiring urgent coronary revascularization occurred in one patient six hours following the completion of the procedure. Another patient developed a new Q-wave on the electrocardiogram and moderate elevation of CPK-MB fraction following the procedure due to loss of a diagonal branch. No deaths occurred in this series. Angiographic restenosis developed in ten patients. In the recurrence group, five had repeat kissing balloon angioplasty, two had repeat single vessel angioplasty, and three patients chose elective surgical revascularization.

Summary

Based on our experience, the technique of kissing balloon coronary angioplasty can be performed safely utilizing the brachio-femoral technique.

Citation Count 55

Key message

The risk of major side branch occlusion can be minimized with this (kissing balloon) technique and the overall complication rate does not significantly differ from that of our experience in single-vessel coronary angioplasty.

Why it's important

This was one of the earliest reports of the "kissing" or simultaneous balloon inflation within the native coronary vessels, a technique that has persisted with the use of coronary stents.

Strengths

The technique described uses two guiding catheters and simultaneous cannulation of the coronary artery with two angioplasty systems.

Weaknesses

Angioplasty equipment was bulky and difficult to steer at this time. These techniques have evolved substantially with the miniaturization of angioplasty equipment.

Relevance

Coronary intervention of bifurcations in which the side branch has significant disease, has remained problematic, despite the use of coronary stents. The risk of side branch occlusion during intervention relates to the extent of the disease within the branch vessel [62], and is due to the snowplowing effect of shifting plaque from the parent vessel to the branch and vice versa. The simultaneous kissing balloon technique described in this series uses dual balloon inflations in the parent vessel and side branch to minimize this effect. Although two guiding catheters were needed with the prototype angioplasty devices, smaller caliber angioplasty catheter soon permitted this procedure to be performed from a single-guiding catheter [63]. Debulking techniques using directional or rotational atherectomy improved procedural success rates and reduced late recurrence [64], but these methods have largely been replaced with coronary stenting [65]. A number of innovative stenting techniques have been described [66,67], but most end with the performance of a kissing balloon inflation. Yet in contrast to the early days, bifurcation stenting can be performed with a single six French-guiding catheter.

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