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Primary angioplasty for acute myocardial infarction in the elderly

[Review in Depth: Acute Coronary interventions in the elderly]

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Outline

Graphics

Abstract

Elderly patients with acute myocardial infarction present a formidable therapeutic challenge. Although there appears to be a survival benefit from thrombolytic therapy for the eligible elderly patient, persistent concerns regarding the risk of intracranial hemorrhage impedes utilization in this age group. Primary or direct angioplasty of the infarct artery has been proven to be an effective modality for reperfusion. Randomized comparisons suggest an advantage over thrombolysis in terms of achieving superior patency and mitigating recurrent ischemic events. Primary angioplasty expands the reperfusion population by including many patients ineligible for thrombolysis and is more effective for treating patients at high risk, such as those with cardiogenic shock. Acute angiography accumulates important prognostic and decision-facilitating information. The benefits of primary angioplasty are more impressive for the aging patient. The survival gain and reduction in intracranial hemorrhage may combine to magnify the advantages of performing angioplasty on patients in this group. Emerging evidence concerning the aging population validates continued examination of this invasive reperfusion approach.

Introduction

Approximately 85% of patients who die from acute myocardial infarction are aged >= 65 years [1]. Because the average age of the population is steadily increasing, precise information regarding the effectiveness of therapeutic intervention for the elderly is needed. Management strategies must take into account the unique characteristics of the elderly infarct patient. Senescent transformation of the cardiovascular system increases the susceptibility to the consequences of myocardial injury. Structural changes to the vasculature lead to an increase in afterload, contributing to hypertrophy of the myocardium and impairment of diastolic function [2].

The elderly patient with infarction presents a diagnostic challenge by arriving later [3] and with a higher likelihood of atypical symptoms [4]. A larger proportion are women and significant comorbidities are more common [3,5]. There is a more frequent history of hypertension, diabetes, congestive heart failure, and previous infarction [6,7].

Age as an independent variable predicts death from myocardial infarction [3,6,7]. The characteristics of elderly people mentioned above certainly influence mortality (15–30%) [6,8], but there is evidence that therapy (particularly revascularization) is less intensively applied in treating patients in this cohort [4,5]. The recent improvement in duration of survival of the elderly infarct patient has been linked to more frequent and intense therapy [8].

Reperfusion of the infarct artery is the principal objective of modern treatment for acute myocardial infarction. Despite overwhelming evidence validating thrombolytic therapy for eligible patients with acute myocardial infarction, there remains doubt and concern regarding the use of thrombolysis in treating the elderly patient.

In an effort to accumulate convincing evidence favoring use of thrombolysis, authors of the majority of trials imposed age-based exclusionary criteria largely because of fears regarding hemorrhagic complications in the elderly population [9]. However, the trials GISSI-I, ISIS-2, AIMS, and ASSET enrolled patients aged >= 65 years. Despite uncertainty regarding subgroup analysis, collective examination of the data demonstrates that there is a survival

advantage for patients treated with thrombolytic therapy compared with control or placebo [10–12]. The relative reduction in mortality might be less than that for younger patients yet a greater absolute number of lives of elderly patients are saved because the overall mortality in this population is significantly higher [10].

Nevertheless, concerns regarding the use of thrombolysis in treating the aged-patient population persist. The proportion of patients who are eligible for thrombolysis declines progressively with age [13,14]. A larger proportion of the elderly may be excluded on the basis of late presentation or electrocardiographic criteria [13]. Among the elderly absolute and relative contraindications for the use of these agents are more frequent [11,13]. The greater prevalence of severe comorbidity among the aged has been shown to reduce the odds of receiving thrombolytic therapy [15].

The fear of hemorrhagic complications for patients in this age group predicates the bias against treatment. The elderly do have a higher incidence of hemorrhagic complications, particularly intracranial hemorrhage, and the additive risk factors (hypertension, a prior cerebrovascular event, and low body weight) for this devastating complication occur more commonly with age [16,17]. Yet, there remains an independent selection bias against thrombolytic treatment of the eligible elderly patient in studies of large populations [15,18]. This reduces the application of important reperfusion therapy to patients in this high-risk population.

Primary angioplasty

The temporally parallel development of angioplasty and intracoronary thrombolytic therapy led to the combined use of these modalities. There was optimism that angioplasty immediately after thrombolysis would enhance salvage of myocardium and mitigate recurrent ischemia through a reduction of the residual infarct artery stenosis. However, this hypothesis was refuted by results of studies demonstrating an increase in mortality and hemorrhagic complications with this approach [19]. The pathologic correlate to these results is represented as harmful intramural hemorrhage when thrombolysis immediately precedes angioplasty [20]. Enthusiasm for early angioplasty of infarctions was restrained by these findings.

Observational studies

Direct or primary angioplasty of the occluded infarct artery without thrombolytic therapy was first reported by Hartzler et al. [21] in 1983. A few centers continued to practice direct angioplasty despite the expansion of thrombolytic therapy. From a meta-analysis of data on 2073 patients (10 series) Eckman et al. [22] reported that average mortality was 8.3% with patency of infarcted artery in 91% of cases. The largest consecutive series (n = 1000) O'Keefe et al. [23] reported an infarct artery-recanalization rate of 94% and a hospital mortality of 7.8%. These series commonly included patients with cardiogenic shock and contraindications to the use of thrombolysis. The more recent Primary Angioplasty Registry (n = 271) of thrombolytic-eligible patients in six centers with experienced staff reported that successful reperfusion in 98% of cases with a hospital mortality of 4% and 6-month cumulative event rates of 6% death, 6% reinfarction, 19% recurrent ischemia and 1% stroke [24].

Randomized controlled trials

Results of three trials comparing primary angioplasty with thrombolysis published in 1993 galvanized the debate regarding reperfusion strategy. Although the PAMI, Mayo Clinic, and Netherlands trials were designed to examine different principal endpoints, combined meta-analysis demonstrated that there was significantly less hospital mortality (2.2 versus 5.8%, P = 0.023) and reinfarction (1.9 versus 7.6%, P = 0.0008) among the angioplasty-treated patients [19,25–27]. Authors of the PAMI trial demonstrated that there was a distinct advantage from angioplasty for patients exhibiting 'high-risk' features (age > 70 years, anterior infarction, and heart rate > 100 beats/min) there being significantly less mortality (2.0 versus 10.4%, P = 0.01) compared with tissue plasminogen activator (t-Pa) thrombolysis [25]. Controversy regarding the statistical power and potential bias in the conduct of these and other small randomized trials has led to considerable debate.

In the GUSTO-IIb angioplasty substudy 1138 patients were randomly allocated to angioplasty or accelerated t-Pa. The primary composite endpoint (death, nonfatal reinfarction, and occurrence of a disabling stroke) occurred in 9.6% of the angioplasty group and 13.7% of the t-Pa group (odds ratio 0.67, P = 0.033) [28]. 'High risk' patients did not appear to benefit in this trial, although acute angiographic success was lower than that achieved in the earlier randomized investigations. After 6 months there was no significant difference between the incidence of the composite endpoint, possibly reflecting late reocclusion in the angioplasty group. Authors of a recent meta-analysis of data from 10 randomized trials (n = 2606, including GUSTO-IIb) derived a 34% reduction in mortality with angioplasty versus thrombolytic therapy (4.4 versus 6.5%, P = 0.02) [29]. Direct angioplasty was associated with a reduction in the total incidence of strokes (0.7 versus 2.0%, P = 0.007) and the incidence of hemorrhagic strokes (0.1 versus 1.1%, P < 0.001). The incidence of death and nonfatal reinfarction was also reduced by angioplasty (7.2 versus 11.9%, P < 0.001). Results of these trials have exhibited a relatively consistent advantage for angioplasty over thrombolysis in terms of improving short-term outcome. However, a degree of uncertainty remains due to the lack of a single statistically powered trial showing that there is a difference in mortality and there are concerns regarding a long-term attenuation of benefit for patients treated with angioplasty.

The Primary Angioplasty Strategy: Examining the Benefits

Beyond the limited comparative trial data one can further consider the advantages of a mechanical reperfusion strategy.

Superior patency

Authors of the GUSTO-I angiographic substudy verified the important link between survival of patients undergoing reperfusion and early attainment of complete (TIMI grade 3 flow) infarct artery patency [30]. A distinct advantage for angioplasty is apparent in that TIMI grade 3 flow is achieved in 73–95% of patients, compared with <= 54% for accelerated t-Pa [24,25,28,30]. Not only is flow restored more often but also significantly less residual stenosis remains after angioplasty [27].

This superior angiographic outcome results in less reinfarction (2–5% with angioplasty versus 4–10% with thrombolysis) [29,31] and recurrence of ischemia. (5–10% with angioplasty versus 10–20% with thrombolysis) [28,31,32]. A less severe residual stenosis could also mitigate adverse ventricular remodeling after infarction [33]. Rates of late reocclusion (9–20%) compare favorably with those reported after thrombolysis (30%) [24,27,34–36].

Restenosis (including late reocclusion), usually within 4 months, has been reported to occur in 31–47% of patients [24,34,35].

Expand the population of patients for reperfusion

A significant proportion of patients are excluded from reperfusion therapy because they are ineligible for thrombolysis. Contraindications (primarily due to hemorrhagic risk) to use of lytic agents are present for 9–35% of patients overall [13,37] and their prevalence increases with age [13,14]. The ineligible-patient classification clearly identifies a high-risk group [38]. Primary angioplasty has been demonstrated to be an effective method for expanding the population of patients eligible for reperfusion therapy [38].

Enhance the efficacy of reperfusion

Analysis of data from the GUSTO-I trial identified previous bypass surgery as a predictor of worse outcome after thrombolysis [39]. A large thrombus burden in vein grafts can resist the action of lytic agents [40]. High rates of success (>= 85%) with primary angioplasty and excellent hospital outcome have been reported for two small series [41,42].

Cardiogenic shock

Patients with a patent infarct artery have a better chance for survival with cardiogenic shock [43]. The efficacy of thrombolytic therapy is diminished in the setting of cardiogenic shock [43,44]. For several nonrandomized series of patients it has been shown that primary angioplasty can lead to improvement of hemodynamic parameters and duration of survival compared to nonreperfused patients [45]. There are concerns regarding selection bias in these studies but overall the efficacy of reperfusion with angioplasty appears to be superior to that with thrombolysis alone. The common presence of multivessel disease in patients with cardiogenic shock can lessen the success of single-vessel direct angioplasty. Primary angioplasty has also been reported to decrease the incidence of mechanical complications after infarction [46].

In the recently completed SHOCK (SHould we emergently revascularize Occluded Coronaries for cardiogenic shocK) trial 302 patients were randomly allocated to intensive medical therapy including use of the intra-aortic balloon pump (86%) and thrombolysis (64%) or an aggressive early approach to revascularization (55% angioplasty, 38% coronary artery bypass grafting) in addition to balloon-pump support [47]. Preliminary results did not reveal a difference in the primary endpoint (30-day mortality) for either strategy. However, a statistically significant reduction in mortality was noted for the revascularization group after 6 months (50 versus 63%, P = 0.027). Revascularization was associated with a lower mortality after 6 months for patients aged < 75 years (65% medical, 45% revascularization, P = 0.02). There was no survival advantage from either approach for patients aged over 75 years, but this group accounted for only 20% (n = 61) of patients enrolled. A larger number of patients might be required in order to definitively exclude the possibility that revascularization confers a benefit for aged patients.

Definitive angiographic data

Emergency cardiac catheterization with planned angioplasty for treatment of acute infarction also allows one to accumulate important risk-stratification information facilitating therapeutic

decisions. Data from the Primary Angioplasty Registry and the PAMI-II trial identified 5% of patients who require emergency bypass surgery for critical multivessel or left-main-coronary-artery disease. Another 5% have spontaneous reperfusion without significant residual stenosis. Patients found to have a low risk at catheterization (age < 70 years without ejection fraction < 0.45, three-vessel disease, and TIMI grade 0–1 flow) have a mortality of 0.4%, allowing early discharge from the hospital [48].

The logistic challenge of primary angioplasty

Despite the promising benefits of primary angioplasty there is concern regarding its applicability to the broad population of patients eligible for reperfusion. Only 18% of hospitals in the USA have cardiac catheterization facilities and even fewer have staff capable of performing cardiac surgery [49]. Primary angioplasty has been performed successfully by practiced operators in hospitals without cardiac surgery facilities [50], yet the relatively frequent necessity of urgent bypass surgery for severe multivessel or left main coronary artery disease (about 5%) and the performance of less experienced programs must be considered.

The results of randomized trials in dedicated institutions have not been reproduced uniformly in some community-based studies including the large MITI registry [51]. In particular the treatment interval, 'door-to-balloon time' (<= 60–90 min), reported for several randomized trials [25–27] is strikingly less than that in many community-based reports (100–180 min) [51,52]. However, although the proportional survival benefit of thrombolysis and angioplasty is clearly greater with early treatment [10,53], even patients undergoing delayed reperfusion may exhibit a low mortality with direct angioplasty [54]. Staff in laboratories dealing with a high volume of cases appear to achieve better rates of success with direct angioplasty, but volume alone does not account for discrepancies among outcomes [55,56] and these differences may impede widespread effectiveness.

Reperfusion by angioplasty in the elderly

The incremental advantage of primary angioplasty is magnified for the elderly. This is illustrated by a statistically significant reduction in mortality for elderly patients treated with angioplasty compared with thrombolytic therapy in pooled analysis of the results of PAMI, Netherlands, and Mayo clinic randomized trials, that is not apparent for younger patients (Fig. 1

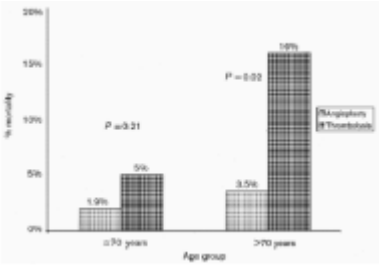

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Fig. 1 Hospital mortality from pooled analysis of the PAMI, Mayo, and Netherlands randomized trials of primary angioplasty versus thrombolytic therapy stratified by age greater than or less than 70 years [31].

) [31]. Notably, in the PAMI trial female gender conferred a greater magnitude of benefit from angioplasty in the elderly patients [57].

Bias against the use of thrombolysis is particularly evident for elderly patients [18]. Thrombolytic contraindications are present nearly twice as frequently for patients in this age group [14]. The near elimination of the peril of therapy-induced intracranial hemorrhage by use of the primary-angioplasty approach might overcome the reluctance to utilize reperfusion therapy in treating many aged patients. It has been estimated that one-third of the reduction in mortality with direct angioplasty compared with thrombolysis is due to a curtailment of the incidence of hemorrhagic strokes [29]. Elderly patients often present later in the course of their infarction and present with diagnostically challenging features [3,4]. The advantages of acute angiographic confirmation and triage also favor the invasive approach.

Despite the apparent advantages of primary angioplasty in treating the elderly there is a paucity of randomized data confirming its superior effectiveness. In the GUSTO IIb trial the improvement of short-term outcome (after 30 days) achieved with primary angioplasty compared with thrombolysis was not secondary to a disproportional benefit for elderly patients [58].

Apart from discouraging results in an early study by Holland et al., there is an increasing number of observational reports demonstrating impressive reperfusion success, similar to that in younger patients, can be attained (Table 1

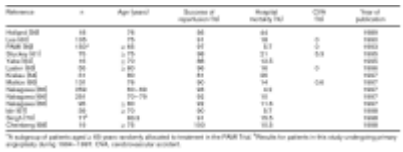

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Table 1 Primary angioplasty series of elderly patients[a] A subgroup of patients aged >= 65 years randomly allocated to treatment in the PAMI Trial. [b] Results for patients in this study undergoing primary angioplasty during 1994–1997. CVA, cerebrovascular accident.

) [59–70]. Mortality rates in the recent studies compare favorably to historical results with thrombolysis. Nakagawa et al. depict an increasing mortality among the more elderly patients. In particular, a high mortality was evident among patients aged >= 70 years for whom reperfusion failed (43–50%) compared with that for the patients aged 60–69 years (10.5%) [66]. Overall these reports support continued utilization of primary angioplasty as a modality for reperfusion of aged patients with acute myocardial infarction. Additional data from the Cooperative Cardiovascular Project identified a lower 30-day mortality among elderly patients treated with primary angioplasty compared to those treated with thrombolysis (11.8 versus 14.3%, $P < 0.001$) [71]. In the NRMI-2 registry combined endpoint of deaths and nonfatal strokes was significantly higher for patients aged >= 75 years administered t-Pa (n = 3731) than it was for those who underwent primary angioplasty (n = 632) (18.4 versus 14.6%, $P < 0.03$) [72]. A prospective randomized trial comparing primary angioplasty with thrombolysis could considerably clarify the reperfusion preference in this high-risk group of patients.

Rescue angioplasty

There remains considerable controversy regarding the role of rescue angioplasty for patients in whom thrombolysis fails [19]. Only one small randomized trial has been conducted (n = 151), showing that the trend for this approach is favorable [73]. Failure of salvage angioplasty

predicts a high mortality and age has been identified as a risk factor for failure of the procedure in one trial [74]. Elderly patients also have a higher risk of hemorrhagic complications after invasive procedures in the setting of thrombolysis. However, this approach remains indicated in selected clinical circumstances, including cases of cardiogenic shock and ongoing ischemia.

Non-Q-wave infarction

Non-Q-wave infarction is a heterogeneous syndrome encompassing transient or permanent coronary occlusion pathophysiologically characterized by varying degrees of plaque rupture, thrombus, and vasoconstriction, which is therapeutically distinct from ST-segment elevation or Q-wave infarction. Application of thrombolysis to effect acute reperfusion in patients with unstable angina and non-Q-wave or non-ST-segment elevation infarction was not found to confer a benefit in the GISSI-I, ISIS-II, and TIMI IIIB trials [75–77].

The effect of early angiography and revascularization compared with a conservative ischemia-driven approach to revascularization for patients with unstable angina and non-Q-wave infarction has been examined in three trials. In the TIMI IIIB trial (n = 1473) proportions of deaths and myocardial infarction with each strategy were similar after 6 weeks. However, the incidence of rehospitalization was less with the invasive approach. Notably the outcomes for prospectively defined subgroups were similar except among patients aged >= 65 years, who experienced a reduction of death or myocardial infarction in those assigned to the early revascularization (7.9 versus 14.8%, P = 0.02) [77].

The invasive strategy in the Veterans Affairs Non-Q Wave Infarction Strategies in Hospital(VANQWISH) trial (n = 920) was associated with more deaths and cases of nonfatal myocardial infarction during hospitalization, but, after a mean follow-up of 23 months, there was no difference between incidences of these endpoints [78]. The surgical mortality of patients in the invasively treated group was 11.6%. No patient undergoing percutaneous transluminal coronary angioplasty in this group died. There appeared to be a moderately strong benefit for the conservative approach in the patients aged >= 60 years.

Results from the recently completed Fast Revascularization During Instability in Coronary Artery Disease (FRISC II) trial (n = 2433, average age 65 years) demonstrated that there were fewer deaths and cases of myocardial infarction after 6 months in the revascularization group (9.4 versus 12.1%, P = 0.031) [79]. This benefit was especially pronounced for men (71% of enrollees; 8.9 versus 13.9%, P = 0.002).

The diverging results of these three trials may illustrate the broad spectrum represented by the syndrome of non-Q-wave myocardial infarction and perhaps the pivotal consequences of the timing of therapy. The tendency toward recurrence of ischemia is manifested by the significant proportion (33–49%) of patients assigned to the conservative strategy who ultimately underwent revascularization. Only in the FRISC II trial were contemporary transluminal revascularization techniques utilized such as stenting (64%) and administration of glycoprotein IIb/IIIa inhibitors (10%). Further study will be necessary in order to refine selection of patients for early revascularization.

Reperfusion therapy in the elderly: future outlook

Extensive investigation has defined the expectations regarding thrombolytic therapy for myocardial infarction. A gradient of risk for hemorrhagic complications was resolved in the therapeutic arms of the GUSTO-I trial [80]. The use of more potent adjunctive antithrombotic strategies to improve results has also enhanced the risk of hemorrhagic strokes particularly in the elderly [81]. Although research continues, the hazard of intracranial hemorrhage might restrict attempts to improve the outcome of reperfusion with thrombolysis.

In contrast, angioplasty techniques continue to evolve, offering considerable potential for improvement in results. Stents have been used increasingly in treating acute myocardial infarction. For several nonrandomized series and small randomized trials procedure success has been improved, with lower rates of reocclusion and restenosis [82]. Authors of the PAMI stent randomized trial (n = 900) reported achieving a reduction in the 6-month composite endpoint (death, reinfarction and target-vessel revascularization) with primary stent implantation compared with angioplasty (12.2 versus 17.3%, P = 0.05) [83]. There are few data available on the age-specific effects of coronary stenting in treating acute infarction. The mortality of patients aged > 70 years was noted to be significantly greater than that of those aged < 70 years (7.1 versus 1.4%, P < 0.0001) in the PAMI stent trial [84]. Mechanical thrombectomy devices for treating acute myocardial infarction are also being investigated [85]. The combination of primary angioplasty or stenting with adjunctive use of glycoprotein IIb/IIIa inhibitors could also improve results of reperfusion [86].

The reperfusion strategy for the elderly patient

Primary angioplasty offers better efficacy and safety for the aged patient than does thrombolysis. Doctors making therapeutic decisions must consider the institutional logistics, experience, and clinical characteristics of patients (Table 2

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Table 2 Primary angioplasty for acute myocardial infarction in elderly patients

). Although the current balance of evidence supports the use of primary angioplasty as the principal modality of reperfusion for the elderly patient, further elucidation of the interventional strategy will require randomized investigation.

Annotated references

• of special interest

•• of outstanding interest

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