Angioplasty as early revascularization in acute myocardial infarction

Akut miyokard infarktüsü sonrası erken revaskülarizasyonda anjiyoplasti

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ABSTRACT

The clinical manifestations characterized by myocardial ischemia due to a sudden decrease in coronary artery flow are defined as “acute coronary syndromes”. These syndromes are classified according to the presence of ST segment elevation on the electrocardiogram (ECG) and the presence of a Q wave. In ST-elevation myocardial infarction (STEMI), the lesion is usually located at the proximal part and the coronary occlusion is complete, myocardial loss is to a great extent, prognosis is poor, and the risk of developing cardiac failure and arrhythmias in the postinfarction period is high. Considering these complications, it is obvious that the immediate provision of reperfusion by opening the completely occluded artery is of vital importance in patients with STEMI. However, a third of these patients are unable to receive reperfusion therapy on time. A considerable number of patients can receive the treatment within 12 hours after the onset of symptoms at best. In cases arriving late, the effectiveness of reperfusion therapy decreases and the risk of mortality and morbidity increases.

Key words: Percutaneous coronary angioplasty, coronary artery bypass surgery, myocardial infarction

ÖZET


Anahtar kelimeler: Perkütan koroner anjiyoplasti, koroner arter baypas cerrahisi, miyokard infarktüsü

Introduction

The clinical manifestations characterized by myocardial ischemia due to a sudden decrease in coronary artery flow are defined as “acute coronary syndromes”. These syndromes are classified according to the presence of ST - segment elevation on the electrocardiogram (ECG) and the presence of a Q wave. In ST - elevation myocardial infarction (STEMI), the lesion is usually located at the proximal part and the coronary occlusion is complete, myocardial loss is to a greater extent, prognosis is poor, and the risk of developing cardiac failure and arrhythmias in the postinfarction period is high. Considering these complications, it is obvious that the immediate provision of reperfusion by opening the completely occluded artery is of vital importance in patients with STEMI. However, a third of these patients are unable to receive reperfusion therapy on time.

A considerable number of patients can receive the treatment within 12 hours after the onset of symptoms at best. In cases arriving late, the effectiveness of reperfusion therapy decreases and the risk of mortality and morbidity increases.
Reperfusion strategies in patients with STEMI are fibrinolytic therapy, percutaneous coronary intervention (PCI) and coronary artery bypass grafting (CABG) surgery.

Percutaneous coronary intervention in the treatment of acute myocardial infarction (AMI) was first applied in 1982 and randomized controlled trials (RCT) have shown that PCI is superior to fibrinolytic therapy in patients with STEMI (3-5).

**Comparison between primary PCI and thrombolytic therapy**

Thrombolytic therapy provides Thrombolysis in Myocardial Infarction (TIMI) grade 3 flows at the 90th minute in the occluded coronary artery in 50-60% of the cases. In 10-20% of the patients, reocclusion occurs in the early period. This rate reaches up to 30-40% in the late period. The most dreadful complication of the thrombolytic therapy is intracranial hemorrhage seen in 1% of patients. The advantage of the thrombolytic therapy is that this treatment can commence immediately, even in an ambulance. Primary PCI provides TIMI grade 3 flows in more than 90% of patients. Re-occlusion and intracranial hemorrhage are rare after PCI (5-8).

According to ACC/AHA guidelines, primary PCI is the method of reperfusion with class I indication in STEMI patients arriving within the first 12 hours after the onset of symptoms in experienced centers where the door-to-balloon time is less than 90 minutes (9). Percutaneous intervention cannot be performed in all patients, the reasons for which are lack of experienced physicians and facilities such as angiography laboratories, the delayed or lack of secure patient transport systems between hospitals, and problems in reimbursement. Furthermore, ACC/AHA STEMI guideline states that fibrinolytic therapy is as effective as PCI in patients with STEMI arriving within the first three hours after the onset of symptoms (9). The CAPTIM and PRAGUE-2 studies have shown that mortality rates in fibrinolytic therapy and PCI are similar in patients arriving within the first 2-3 hours after the onset of symptoms (10, 11). However, in patients arriving within 3-12 hours after the onset of symptoms, the first choice treatment should definitely be PCI. Besides, PCI should be the treatment of choice in patients older than 75 years of age with an increased risk of intracranial hemorrhage, in patients with cardiac failure, in those with hemodynamic and electrical instability, and in patients with a clinical picture of cardiogenic shock (9).

An analysis (12) of 23 randomized clinical trials comparing PCI with fibrinolytic therapy, showed that the majority of cases in the thrombolytic therapy group were given fibrin-specific agents. Death in the early period was found to be 7% vs. 9% (p=0.0002), non-fatal reinfarction -3% vs. 7% (p=0.0001), stroke -1% vs. 2% (p=0.0004), and cerebral hemorrhage - 0.05% vs. 1.1% (p<0.0001). Thus, primary PTCA was proven to be more effective than thrombolitics in the treatment of STEMI by providing 25% reduction in death, 40% reduction in reinfarction, 50% reduction in stroke, and 95% reduction in cerebral hemorrhage (12). Unfortunately, not all patients with AMI can reach PCI centers. In a meta-analysis (13) of six studies including patients with STEMI arriving at hospitals where PCI was unavailable, the effects of on-site thrombolytic therapy were compared with relatively delayed PCI after a patient is dispatched to another center. The transfer time was less than three hours. In the follow-up, reinfarction was 68% (p=0.001) less prevalent and stroke was 56% (p=0.015) less prevalent in the group undergoing PCI, than in the group undergoing thrombolytic therapy. Although there was a tendency of a decrease (19%) in all causes of mortality, it was not significant (p=0.08) (13). This meta-analysis showed that primary PCI, even if delayed, is superior to thrombolytic therapy in STEMI.

The grade of TIMI flow in the occluded artery after reperfusion therapy is one of the parameters affecting mortality and morbidity after STEMI. TIMI grade 3 flow in the occluded artery was provided in 50-60% of patients by fibrinolytic therapy, whereas this rate was over 90% with PCI (14). Thirty-day mortality was 4.6% and two-year mortality was 7.9% in patients in whom TIMI grade 3 flow was provided in the occluded artery, while in patients with TIMI grade 0-2 those rates were 8% and 15.7%, respectively (15).

The lower mortality and morbidity with PCI than with thrombolytic therapy in AMI is due to provision of a high TIMI flow in a short time. Intracranial hemorrhage is a serious complication of thrombolytic therapy. In the meta-analysis mentioned above, the prevalence of hemorrhagic stroke was 1% in the fibrinolytic therapy group, whereas it was 0.05% in the PCI group (12). Approximately one-third of the reduction in mortality in PCI compared to that of fibrinolytic therapy is due to absence of intracranial hemorrhage (16).

**PCI treatment methods**

Previously, primary PCI was performed using only balloon angioplasty in AMI. Acute and subacute occlusions, elastic recoils, coronary dissections and restenosis in the late period diminish the effectiveness of treatment in elective percutaneous transluminal coronary angioplasty (PTCA). The rate of restenosis is approximately 50% and that of reinfarction is 3-5% after primary PTCA. The use of effective antiaggregant therapies and the procedure of stent implantation under high pressure have improved the angiographic and clinical outcomes of elective PTCA with stenting compared to PTCA without stenting. Thus, stent implantation has been added to primary PTCA.

In a study comparing patients undergoing primary PCI with angioplasty alone or added stent implantation, there was no significant difference in mortality. However, restenosis rate (33.5% vs. 20.3%) (p<0.001), angina (16.9% vs. 11.3%) (p=0.02) and reintervention to the target artery (17% vs. 7.7%) (p<0.001) were lower in the stent group as compared with PTCA alone group (17, 18). As many other studies have also supported that clinical and angiographic outcomes were better with primary stent implantation than those with primary PTCA, today, primary stent implantation is more frequently performed.

As direct stent implantation decreases the procedure time, radiation period and costs, it is frequently used in elective PCI. It was considered that with direct stent implantation in AMI, there would be better myocardial perfusion and less myocardial injury.
due to plaque embolization and decrease in no-reflow. In a study comparing direct stent implantation with angioplasty and stent implantation, 50% of the cases were not eligible for direct stent implantation. The TIMI flow and corrected TIMI frame count were similar in both groups. ST segment resolution was better in direct stent implantation; however, there was no significant difference in mortality between the two groups (19). The advantages of direct stent implantation in AMI are short procedure time and low cost; however, one of the complications is failure in stent implantation (improper localization or inability to cover the whole lesion), especially with inexperienced operators.

**Conditions where PCI is more effective**

Many studies have searched for answer to the following questions: which patients benefit most from primary PCI and what are the requirements for percutaneous reperfusion?. In the DANAMI-2 study, PCI and thrombolytic therapy were compared in high-risk (TIMI risk score ≥5) and low-risk (TIMI risk score<4) patients. In the three-year follow-up, the mortality rate in high-risk patients was 25.3% in the PCI group, whereas it was 36.2% in the thrombolytic therapy group (p=0.02). However, they were 8% vs. 5.6%, respectively, in the low-risk patients (p=0.11). When the composite end-point of death, reinfarction, and disabling stroke is used, there was no difference in effect between primary angioplasty and fibrinolysis in the low-risk group (13.7% versus 15.7; p=0.30) , but there was a significant reduction in events with primary angioplasty in the high-risk group (32.3% versus 45.9; p=0.004) (20). In the PAMI trial, PCI and tissue plasminogen activator (t-PA) as thrombolytic therapy were compared in STEMI (21). In-hospital mortality in anterior myocardial infarction was found to be 1.4% for PCI and 11.9% for the thrombolytic therapy (p=0.01). Recurrent myocardial ischemia was 11.3% vs. 28.4%, respectively (p=0.01). The results were significantly in favor of PCI. The mortality rates were similar in both treatments in non-anterior myocardial infarction (3.2% vs. 3.8%; p=0.82) (21). In another study assessing the effect of PCI relative to the thrombolytic therapy in anterior AMI, PCI and alteplase were compared (7). There was a significant decrease in in-hospital mortality in the PCI group (2.8% vs. 10.8%, p=0.02). Post-infarct angina and positive exercise test were also significantly lower (11.9% vs. 25.2% (p=0.01) and patients in PCI group less frequently underwent percutaneous or surgical revascularization after the initial treatment. Revascularization rate was 22% vs. 47.7% (p<0.001) and six-month mortality was 4.6% vs. 11.7% (p=0.05) in favor of PCI (7). All these studies have shown that PCI was more effective than thrombolytic therapy, especially in high-risk patients and in patients with anterior MI.

**Elderly patients**

Although the effect of fibrinolytic therapy was decreased in elderly patients, its effect of decreasing mortality continues when compared to conservative treatment. However, considering the risk of intracranial hemorrhage, half of the patients do not receive fibrinolytic therapy. The risk of intracranial hemorrhage was found to be 2.5% in patients over 75 years of age in the NRMI-2 study (22). Similarly, combination therapies aiming at increasing the effectiveness of fibrinolytic therapy in ASSENT-3 and GUSTO-V studies did not increase the general effectiveness but increased the risk of hemorrhage in patients over 75 years of age (23, 24).

There have been no comprehensive and large-scale studies comparing PCI and thrombolytic therapy in elderly patients. Available data were derived from subgroups of large-scale studies. In a study of 80,356 patients when PCI was compared to thrombolytic therapy, in the subgroup analysis of 20,683 elderly patients, the 30-day mortality was found to be 8.7% vs. 11.9% (p=0.001), and one-year mortality was found to be 14.4% vs. 17.6% (p=0.001) (25). The NRMI-2 registry study found that PCI was superior to fibrinolytic therapy in patients over 75 years of age for combined end-points as in-hospital mortality and non-fatal stroke (14.6% vs. 18.4%) (p=0.003) (22).

In the PAMI study comparing PCI and thrombolytic therapy, 38% of patients were >65 years of age. In the subgroup of elderly patients, the reduction in in-hospital death or reinfarction with angioplasty versus t-PA was particularly marked in patients > or=65 years of age (8.6% vs. 20.0%, p=0.048) (26).

In the still unpublished SENIOR-PAMI trial, in a subgroup analysis of patients stratified by age, among patients 70-80 years old, there was a nonsignificant 38% reduction in death, a nonsignificant 36% reduction in death/cerebrovascular accident, and a significant 55% reduction in the combine end-point of death/cerebrovascular accident/reinfarction (27).

In the GRACE study, fibrinolytic therapy was contraindicated in 15% of the 2084 patients and 30% of the patients over 75 years of age could not undergo reperfusion treatment (2). The cases not receiving fibrinolytic therapy were the high-risk group patients, such as those over 75 years of age, with history of MI or CABG surgery, with diabetes mellitus or congestive heart failure, and they probably benefit more from PCI.

The MITRA registry study compared the patients receiving PCI due to contraindication of fibrinolytic therapy and patients receiving conservative therapy, and found that mortality was significantly lower in the PCI group (2.2% vs. 24.7%) (p=0.001) (28).

**PCI in mechanical complications**

When PCI was compared to fibrinolytic therapy as indication for mechanical complications occurring after AMI in the combined meta-analysis of GUSTO-I and PAMI I/II studies, it was found that mechanical complications were decreased by 86% in the PCI group (29).

There was a significant decrease in acute mitral regurgitation (0.31% vs. 1.73%) (p<0.001) and ventricular septal defect (0.0% vs. 0.47%) (p<0.001). In the multivariate analysis of another study including 1375 patients, PCI was found to be an independent factor preventing left ventricular free wall rupture (30).

**Cardiogenic shock**

Cardiogenic shock complicates 6 to 7 percent of AMI cases. Early shock is defined as the shock seen on arrival of the patient and the prevalence is about 1%. Late shock develops at the...
hospital and the prevalence is about 5-6%. The mean time from the onset of symptoms to shock in patients with STEMI is 9 to 10 hours. The mortality rate was reduced from 80-90%, to 50-60% with intraaortic balloon pump (IABP) support and opening of the occluded artery in patients with shock. One of the most important factors for the reduction of mortality is the immediate revascularization. In the SHOCK study, early intervention in patients with shock had a mortality rate of 60%, whereas it was 82% for the late intervention group (p<0.001) (31).

In the same study, the mortality rate for early intervention in patients with late shock was 46%, whereas this was 62% for the late intervention group (p<0.001). The reduction in the thirty-day mortality was more prominent in young patients with shock (41% vs. 57%, p<0.05). Hence, young patients in shock should undergo immediate revascularization. Among patients arriving in cardiogenic shock, 15-20% had a left main coronary artery (LMCA) lesion and 50-60% had serious three-vessel disease (31).

When PCI is planned for patients with AMI and in cardiogenic shock, intervention should only be limited to the infarct-related artery first. Some patients have multivessel disease, if the shock does not improve after opening the infarct-related artery or if hypokinesia persists in another zone, not supplied by the infarct-related artery, intervention should be performed to these arteries if the coronary artery anatomy is convenient. In the SHOCK study, the thirty-day mortality rates (p=0.86) and one-year mortality rates (p=0.71) were similar in patients undergoing PCI and coronary artery bypass surgery (CABG) (31).

The number of diabetic patients, the rate of LMCA lesions and those with three-artery disease was higher in the CABG group than in PCI group. However, in the presence of convenient coronary anatomy for the practical advantages and provision of early reperfusion, the choice of revascularization treatment method should be PCI with the support of IABP.

**Late PCI**

Of the all AMI cases, 9-31% arrives after 12 hours and in 65% of these cases, the infarct-related artery is occluded (32). According to the 2004 ACC/AHA guidelines, PCI is recommended only if there is persisting ischemia, serious heart failure, hemodynamic and electrical instability (9). Various studies have been planned considering that the infarct area will diminish, the electrical stability will be provided, and the survival will improve with collateral circulation to other probable ischemic sites (open-artery hypothesis) after opening the infarct-related artery in asymptomatic cases and in cases in which the infarct-related artery is completely occluded (33). Three studies examining the effect of routine primary PCI in late-arriving patients (12 hours to 28 days) and in asymptomatic patients were conducted: BRAVE-2, DECOPI, and OAT (34-36). Although there was some benefit in some studies for the left ventricular systolic functions, none of them had significant clinical benefit.

**Limitations of the primary PCI**

Despite provision of TIMI-3 flow by primary PCI in more than 90% of cases, adequate TIMI flow cannot be maintained in 7% of cases (TIMI flows<2) and the prognosis in these cases is poor (37). The reasons for the TIMI flow grade being <2 are: thrombus, persistence of severe occlusion in the coronary artery, dissection, spasm and distal macroembolization, inappropriate stent implantation, acute stent thrombosis, reperfusion damage, capillary and myocyte edema, and no-reflow phenomenon. No-reflow is defined as a TIMI flow grade of ≤2 in the distal coronary artery in the lack of macrovascular obstruction. It is an uncommon cause of suboptimal reperfusion. Possible causes are: distal embolization of plaque or thrombus, microvascular damage, myocardial necrosis, stunning, reperfusion damage due to the generation of oxygen-free radicals, free tissue factors from dissecting plaque, and alpha adrenergic-mediated vasoconstriction (38-41).

Direct stent implantation decreases the likelihood of suboptimal reperfusion (no-reflow), but the effects of glycoprotein IIb/IIIa inhibitors could not be demonstrated. Various new devices have been developed to avoid the no-reflow phenomenon. Distal embolic protection devices have been found effective in saphenous vein grafts, but not in native coronary arteries (42, 43). The effectiveness of thrombectomy devices has not been completely agreed upon (44, 45). Although treatment for the possible underlying etiological causes is recommended in cases with inadequate TIMI flow grade after primary PCI, there is no effective treatment for no-reflow occurring in cases with patency of the proximal coronary artery.

**Drug-eluting stents in STEMI**

Drug-eluting stents reduce the rates of re-stenosis and the need for revascularization for the target artery, as compared with uncoated stents in elective PCI. Today, drug-eluting stents are being used off-label, although not strongly recommended in AMI. The TYPHYOON and PASSION trials were performed to compare uncoated and drug-eluting stents in PCI in patients with AMI (46, 47). The TYPHYOON study included 712 patients and compared sirolimus-eluting stent with the uncoated stent. The rate major coronary events (MACE) was significantly less in favor of sirolimus-eluting stents compared to uncoated stents (5.9% vs. 14.6% (p<0.001), target lesion revascularization (TLR) rate was 3.7% vs. 12.6%, (p<0.0001), and restenosis rate was 3.5% vs. 20.3%, respectively (p<0.001) (46). The PASSION study, comparing the paclitaxel-eluting stent with the conventional stent, included 619 patients (47). The MACE (6.7% vs. 12.6%, p=0.12), death, MI (4.8% vs. 6.5%, p=0.39), and TLR (6.2% vs. 7.4%, p=0.23 rates were similar in two groups (47). In a meta-analysis (48) of seven studies with a mean follow-up of 8 to 12 months comparing 2357 patients, drug-eluting stents were compared to bare metal stents in patients with AMI in terms of cardiac events (death, MI, revascularization) rates: for death - 9.3% vs. 17.6%, relative risk (RR)=0.53, 95% CI 0.43-0.66), for MI - 5.8% vs. 6.9%, (RR=0.94, 95% CI 0.62-1.15), stent thrombosis - 2.3% vs. 2.6% (RR=0.87, 95% CI 0.53-1.45), and for TLR - 4.8% vs. 12%, (RR=0.40, 95% CI 0.30-0.54) (48). In the light of this meta-analysis, we can conclude that although drug-eluting stents reduce the need for revascularization, they do not have any effect on death or MI.
In these studies with short-term follow-up (one year), restenosis, MACE and TLR rates were lower in drug-eluting stents; however, with no effect on mortality. Although there is no increase in early stent thrombosis in drug-eluting stents, there is lack of evidence for its safety in the late or very late stent thrombosis. In a large registry including 23500 patients undergoing drug-eluting stent implantation, AMI was considered the most important factor for early and late stent thrombosis (49). In another study, although stent thrombosis in drug-eluting stent use in patients with AMI was attributed to the lack of effective thienopyridine therapy, today, drug-eluting stent treatment is not considered safe in STEMI (50).

**CABG in STEMI**

Coronary artery bypass grafting surgery has longer event-free survival than PCI, and has less recurrent ischemia and the need for reintervention. It has the advantage of complete revascularization, but PCI has been the first choice of therapy in STEMI due to practical advantages. Maximum myocardial protection is within the first six hours in AMI treatment. Unfortunately, even with more practical PCI this aim is hardly achieved. It is difficult to organize the team and operation room for CABG especially during out-of-hours. Provision of reperfusion takes longer than that of PCI.

Indications for CABG surgery in AMI are as following: cases with inconvenient coronary artery anatomy for PCI, persisting ischemia and large myocardial tissue at high risk. Surgical revascularization is not frequently used as the method of primary reperfusion in AMI. In PAMI-2 study, only 44 (4.4%) out of 1100 patients did not have a convenient coronary artery anatomy for PCI (severe multiple artery disease, LMCA disease), and these patients underwent surgical reperfusion. The mortality rate of emergency CABG surgery is 6.4%, whereas it is 2% for the elective surgery (51). A few studies have shown that reperfusion damage and mortality increase if CABG surgery is performed within the first six hours in patients with AMI (52-53).

In-hospital mortality in cardiogenic shock in patients with AMI is 33% when the infarct-related artery is open and is 75% when it is occluded (54). In the SHOCK study, it was shown that especially in young patients, the mortality rate was reduced to 41% in patients with shock and AMI when early revascularization was performed (55). Although the results for the treatment of shock are good, CABG surgery is not widely used in daily practice. The mortality in cardiogenic shock in AMI was 60.3% in 1995. It was reduced to 47.9% in 2004 (p<0.001). In this period, the PCI rate increased from 27.4% to 54.4% (p<0.001), but CABG increased only from 2.1% to 3.2% showing a steady progress (56). With improvement and experience in interventional cardiology and the development of new technologies acute complication rates have decreased to 2-4% with PCI in patients with AMI. In such complications, if there is a persisting pain, hemodynamic instability, if the coronary artery anatomy is convenient for CABG surgery and if the procedure will reduce myocardial damage and mortality and morbidity, then CABG surgery can be preferred (57). In cases when thrombolytic therapy fails, PCI is frequently performed, but those cases are rarely suitable for CABG surgery. In cases undergoing CABG surgery just after the fibrinolytic therapy, major hemorrhage and perioperative morbidity and mortality are increased. In a TIMI-II study, 290 patients underwent CABG surgery within 24 hours or later. Perioperative mortality was 17% vs. 4% (p<0.001), and major hemorrhage was 74% vs. 51% (p=0.002) in patients underwent surgery as compared without surgery (58). Early surgical revascularization after failed thrombolytic therapy increases the mortality.

As effective reperfusion methods are commonly used in AMI, ventricular septal defect (VSD) related to infarct, left ventricular wall rupture and acute mitral insufficiency due to papillary muscle rupture are rarely seen compared to the past. In the GUSTO-I study (59) including 41021 patients, post-infarct VSD rate was 0.2%, and 40% of patients underwent surgical repair in 3.5 days after the infarct. The thirty-day mortality and one-year survival rates were 53% and 47%, respectively. They were 6% and 3%, respectively, in the medical treatment group (59). Patients with post-MI VSD should undergo immediate surgical repair. Overall, 44365 patients were included in a retrospective study investigating the effect of time between the onset of symptoms and surgical revascularization in AMI (53). It was shown that the mortality rate decreases as the time between MI and CABG increases. It was 11.8% for the first six hours, 9.5% for the 6th to 23rd hours, 4.3% for 1st to 7th days, 2.4% for 8th to 14th days and 2.6% for more than 15 days (53). Therefore, surgical reperfusion is limited in the acute period of STEMI with mechanical complications, PCI complications or LMCA disease not eligible for PCI, and patients with cardiogenic shock with serious three artery disease with inconvenient coronary artery anatomy for PCI.

**Conclusion**

The most important factor determining the survival after MI is the immediate provision of coronary blood flow. However, approximately 30% of patients with STEMI cannot receive reperfusion treatment on time. The optimal treatment for reducing the morbidity and mortality, for protecting left ventricular function, and for decreasing the infarct area in patients with STEMI, is prompt reperfusion in the infarct-related artery using fibrinolytic therapy or PCI. Several RCT have shown that the first choice of treatment should be PCI in experienced centers, where the door-to-balloon time is less than 90 minutes when compared to fibrinolytic therapy. Cases with high TIMI risk scores and with anterior MI should have priority for PCI. The safety of drug-eluting stents in STEMI has not been proven yet. The utilization of urgent CABG surgery in patients with STEMI is limited due to the 3-fold higher mortality rate for urgent surgery than for elective surgery, and due to fact that as the time between the onset of STEMI and CABG surgery shortens the mortality risk increases.
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