Original Articles

Implementation of Guidelines for the Treatment of Acute ST-Elevation Myocardial Infarction
The Cologne Infarction Model Registry

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Background—The aim of the Köln (Cologne) Infarction Model is to examine the feasibility of obligatory treatment of ST-segment–elevation myocardial infarction (STEMI) by first-line percutaneous coronary intervention.

Methods and Results—The study was performed in Cologne with >1 million citizens, 5 coronary intervention centers, and 11 primary care hospitals. Twelve-lead ECG was available for all emergency medical service (EMS) teams. Partners guaranteed direct transfer of STEMI patients to a catheterization laboratory. A total of 519 patients treated within KIM in 2006 were included in the study. Of these, 24% presented at a primary care hospital, 11% presented directly at a coronary intervention center, 5% were transferred by EMS to primary care hospitals, and 60% were directly transferred by EMS to a catheterization laboratory. In 91% of cases, the catheterization laboratory was notified of the patient's arrival in advance. False-positive ECG diagnosis of STEMI by EMS accounted for 6%. Median treatment times were as follows: from the start of symptoms to first medical contact, 120 minutes; phone to balloon, 70 minutes; and door to balloon, 49 minutes. Of all patients, 93% underwent angiography; 409 patients were treated by coronary intervention, and 24 underwent emergency coronary artery bypass graft. Thrombolysis in Myocardial Infarction grade 3 flow was obtained in 89%. In the hospitals, deaths and new myocardial infarctions were observed in 12.1% and in 1.9% of all patients, respectively.

Conclusion—The Cologne Infarction Model provides evidence for the feasibility of obligatory treatment of STEMI by primary coronary intervention in a metropolitan setting. Acceptance of treatment pathways allowed nearly all STEMI patients to undergo coronary angiography. ECG competence of EMS was excellent. Treatment times were within postulated limits. Results, including mortality, were within a high quality range. (*Circ Cardiovasc Intervent*. 2008;1:95-102.)

Key Words: angioplasty ■ catheterization ■ emergency service ■ guideline ■ myocardial infarction

Primary percutaneous intervention (PCI) has been shown to be superior to fibrinolytic therapy in patients with ST-segment–elevation myocardial infarction (STEMI). The benefit of PCI is most pronounced when it is performed early after the onset of symptoms and close to the patient's first contact with medical professionals.[1,2] This evidence has been reflected in recent guidelines for the treatment of acute myocardial infarction,[3,4] recommending PCI as first-line therapy provided that the time between the first medical contact and the first balloon inflation or the time between entering the hospital and the first balloon inflation is <90 minutes and the delay between the potential start of fibrinolytic therapy and the percutaneous coronary intervention is <60 minutes.

Clinical Perspective see p 102

In Germany, a number of hospitals provide a 24-hour coronary catheterization laboratory, and organized networks exist to guide patients with an acute STEMI into the catheterization laboratory without any delay.[5] However, precise data concerning the clinical results of these efforts remain sparse. For the United States, it has been reported that less than one third of patients with STEMI receive primary PCI and that <40% are treated within 1.5 hours.[2,6–8] This holds true despite the fact that, in several regions, both triage and transfer protocols for PCI in patients with STEMI have been developed.[2] Thus, there is no broad evidence in the literature

proving the feasibility of PCI as first-line therapy in patients with STEMI.

Cologne is a German city with a population of >1 million citizens. Within the city, there are 5 cardiology departments with a cardiac catheterization facility equally distributed throughout the city and 11 primary care hospitals without a catheterization facility. The emergency medical service (EMS) is centrally organized, and 12-lead ECG is available for all EMS teams. Thus, Cologne provides ideal conditions for the implementation of STEMI treatment guidelines. For >10 years, PCI has been offered as first-line therapy for myocardial infarction by some cardiology departments. However, it was not until autumn 2005 that the efforts of the central emergency service and of all hospitals within the city were coordinated to provide treatment of patients with STEMI according to the guidelines. The Köln (Cologne) Infarction Model (KIM) was founded, establishing a triage and transfer protocol guiding STEMI patients to a catheterization laboratory in the fastest way possible. The efforts of the network were accompanied by a registry documenting all important treatment steps, serving as a measure of quality management and a scientific evaluation. This report is the first presentation of the registry data, providing evidence that, at least in an ideal urban setting, the requests of the recent European and US guidelines can be fulfilled. A new aspect of this registry is that the complete medical system, including all hospitals within a city, can be involved and can adhere to strict quality management guidelines. KIM is self-financed and works independent of health insurances and political health administrations.

Methods

Patient Population

The data reflect 519 patients treated within KIM between January and December 2006. The aim of KIM was to collect data of patients with STEMI who were treated within the medical system of Cologne, regardless of whether they were treated in a catheterization laboratory. Inclusion of patients in the KIM registry occurred after initial diagnosis of STEMI, regardless of whether this was done by an emergency physician outside a hospital, by a physician in a hospital without a catheterization laboratory, or in a cardiology unit with a catheterization laboratory. Inclusion was based on the 12-lead ECG criteria, including ST-segment elevation of ≥0.1 mV in ≥2 depending extremity leads, ST-segment elevation of ≥0.2 mV in ≥2 neighboring chest leads, or left bundle branch block in combination with typical symptoms.

Transfer Triage and Treatment Protocol

Before the start of KIM, the metropolitan EMS, all 11 hospitals without a catheterization unit, and all 5 centers with a catheterization unit agreed that patients diagnosed with STEMI should no longer be transferred to the respective district hospital. Instead, they should be transferred directly to a cardiology unit with catheterization facility. The cardiology units were obliged to provide a catheterization laboratory and emergency care unit available 24 hours a day and 7 days a week. Activation of the catheterization laboratory and its staff had to be started after the diagnosis of STEMI by first medical contact. Thus, the mobilization of catheterization laboratory staff occurred immediately after the announcement of a patient's transfer to the catheterizing hospital or after the patient's arrival at this site. EMS physicians diagnosing STEMI were asked to inform the respective catheterization laboratory by phone and to deliver the patient directly to this facility. Admitting physicians in noncatheter-
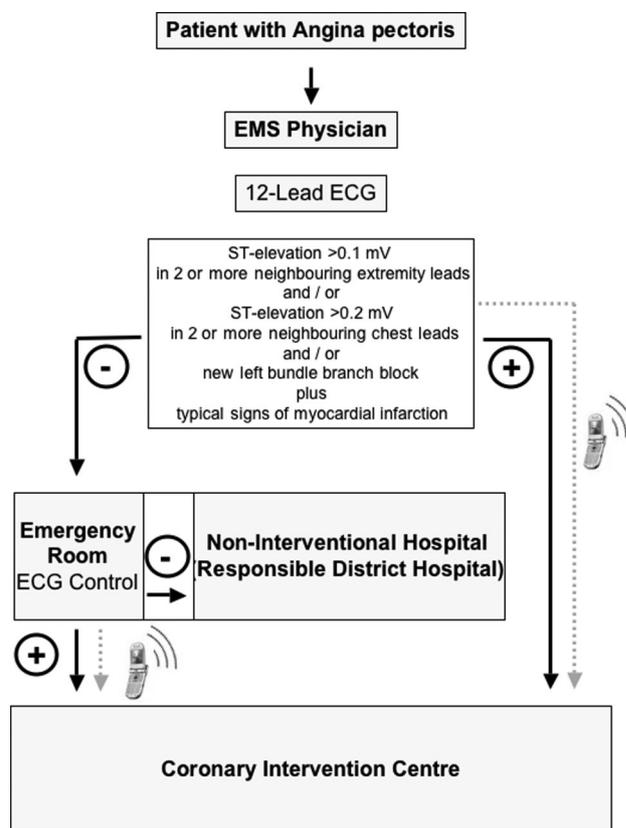

Figure 1. Triage for patients with STEMI in KIM.

izing hospitals diagnosing STEMI were also asked to inform the cooperating cardiology unit and to transfer the patient to its catheterization laboratory without any delay. Patients presenting at the emergency department of a hospital with a catheterization laboratory had to be transferred directly for coronary angiography and interventional treatment. The proposed patient pathway is shown in Figure 1.

To ensure ECG competence of the EMS doctors (most of them were medical doctors, but only some were internal medicine doctors or cardiologists), the start of KIM was accompanied by a special ECG teaching campaign for the EMS staff. Also, all EMS teams and all cooperators within KIM were supplied with a specific handbook summarizing the actual recommendations for STEMI diagnosis and therapy as well as standard operating procedures reflecting the special situation in Cologne.

Initial treatment of the patient either by the EMS or the first admitting hospital included 5000 IE of intravenous heparin, 500 mg of aspirin, 600 mg of clopidogrel, and oxygen inflation. Depending on the patient's pain and stress, opioids and diazepam could be given. Hemodynamically stable patients were allowed to be treated with 2.5 to 5 mg of metoprolol or an equivalent dose of another β-blocker. In cases of hypertension and left ventricular decompensation, treatment with nitroglycerol (0.8 mg sublingual) was recommended. In cases of hemodynamically stable ventricular tachycardia, treatment with amiodarone was recommended. Resuscitation was performed according to international standards, if necessary.

Patients were treated within the catheterization laboratory according to international standards. Facilitated acute PCI was not recommended. Bare-metal stents were regarded as standard, and drug-eluting stents were available but not favored. The use of GpIIb/IIIa antagonists was not excluded but was also not specifically enforced as standard.

Data Collection and Quality Management

Each patient included in the KIM treatment regimen was accompanied by a file consisting of 7 separate protocol forms for each

potential treatment step: checklist of first medical contact, EMS treatment, admitting hospital without catheterization laboratory, catheterization laboratory intervention center, discharging hospital without catheterization laboratory, and a follow-up questionnaire addressing general practitioners 3 and 12 months after hospital discharge. These forms guaranteed collection of important patient information throughout the complex medical system. Doctors treating the patient at the individual steps were asked to complete the forms, which takes <2 minutes. Missing data were added by a secondary study of the patient's hospital files. All data were transferred to an electronic database that was blinded as to patient's names and personal data.

Central parameters for the evaluation of KIM were as follows:

- quality of data documentation
- adherence to treatment pathways
- correctness of primary diagnosis
- reaction times:
- time between first symptoms and first medical contact (symptom to contact)
- time between first medical contact and intracoronary balloon inflation (contact to balloon)
- time between first announcement of patient at the catheterizing hospital and intracoronary balloon inflation (phone to balloon)
- time between arrival at catheterizing hospital and puncture of femoral artery (door to needle)
- time between arrival at coronary intervention hospital and intra-coronary balloon inflation (door to balloon)
- angiography and intervention rate and results of interventional treatment (Thrombolysis in Myocardial Infarction [TIMI]grade 3)
- in-hospital major adverse cardiovascular events
- secondary preventive medication at discharge and follow-up (3 and 12 months after STEMI).

Retrospective Analysis of Treatment Parameters Before the Start of KIM

To provide comparable quality parameters for the time period before the start of KIM, a retrospective analysis of STEMI patient data at 2 intervention centers during the 6 months before the start of KIM was performed. Altogether, the files of 308 patients were analyzed. Because of STEMI, these patients were treated at the 2 biggest coronary intervention centers in Cologne, University Hospital and St Vincenz Hospital, from January to June 2005, before the start of KIM. Parameters of interest were treatment times and mortality.

Statistics

The software package SPSS version 12 (SPSS Inc, Chicago, Ill) was used for all statistical analyses. Before the statistical analyses, Kolmogorov-Smirnov tests for normality were performed, and the respective variables were analyzed accordingly. Descriptive data are given as median (interquartile range [IQR]) or mean±SD, if appropriate. A plausibility check was performed for each individual parameter variable for which the authors had access to the original patient treatment file. Statistical comparison of the treatment times between interventional centers and overtime was based on Kruskal-Wallis tests (Figure 2), whereas χ^2 tests were performed for comparison of mortalities (Figure 3; see Table 3). The trend test used in Figure 3 was based on a weighted linear regression of the mortalities on a score defined by the age groups.

Results

Patient Characteristics

Between January 1, 2006, and December 31, 2006, 519 patients were included in KIM. The number of participating patients was equally distributed throughout the whole year. The smallest number of individuals included in KIM was 36 (in September); the maximum number was 51 (in February).
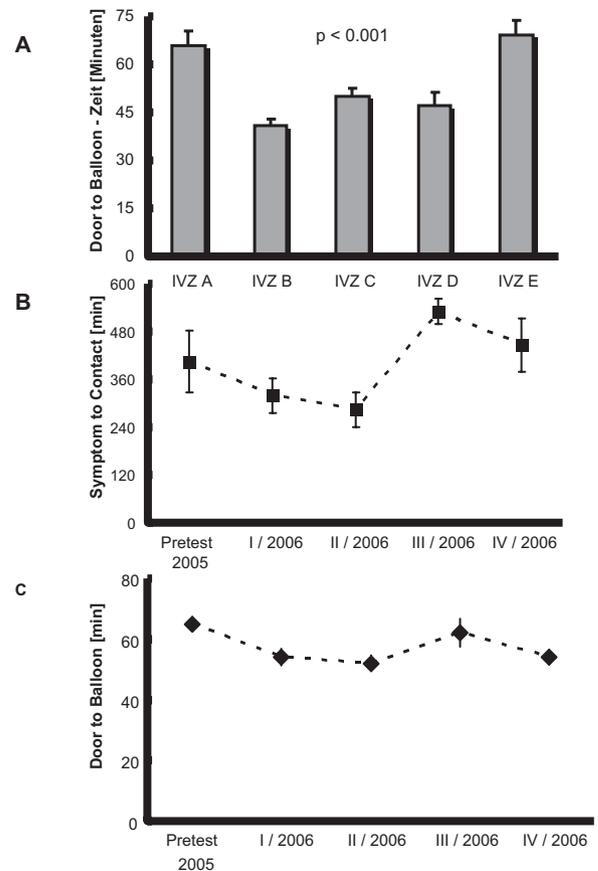

Figure 2. Reaction times in KIM in the first to fourth quarter of 2006 and in a pretest phase from September to December 2005. This 4-month pretest phase was used to educate all KIM partners about the patient pathways and standard operation procedures. A, Mean door-to-balloon times in the 5 participating centers. B, Time between the onset of symptoms and the first medical contact (symptom-to-contact time). C, Time between arrival at the coronary intervention center and balloon inflation (door-to-balloon time). All data are given as median±SE.

Of all patients, 356 patients were male and 163 were female. The mean age of the patients was 63.4±13.9 years; 37.6% of the patients were between 65 and 79 years of age, and 13.3% of the patients were ≥80 years of age.

At primary contact with the medical system, 15.2% of the patients presented with signs of cardiogenic shock, defined as either cardiac arrest (6.5%) or severe inotropic failure (8.7%). In all these patients, ECG diagnosis of STEMI was confirmed by a qualified cardiologist. In addition, 74% of these patients revealed a significant increase in creatinine kinase. The remaining 22 patients died early in the catheterization laboratory, and no blood samples were obtained before death. In 13.3% of all patients, resuscitation was performed by the EMS team, and in 14.7% of all patients, intubation and ventilation were necessary before transfer to the intervention center. Of all patients, 8% revealed a positive shock index with systolic blood pressure <100 mm Hg and pulse rate >100 bpm. Catecholamines were given to 16.6% of patients during transport from the EMS to the intervention center, and 5.6% of patients had to be resuscitated during this transport. On admission to the intervention center, 15.2% of patients were dependent on catecholamines, 13.0% were ventilated,
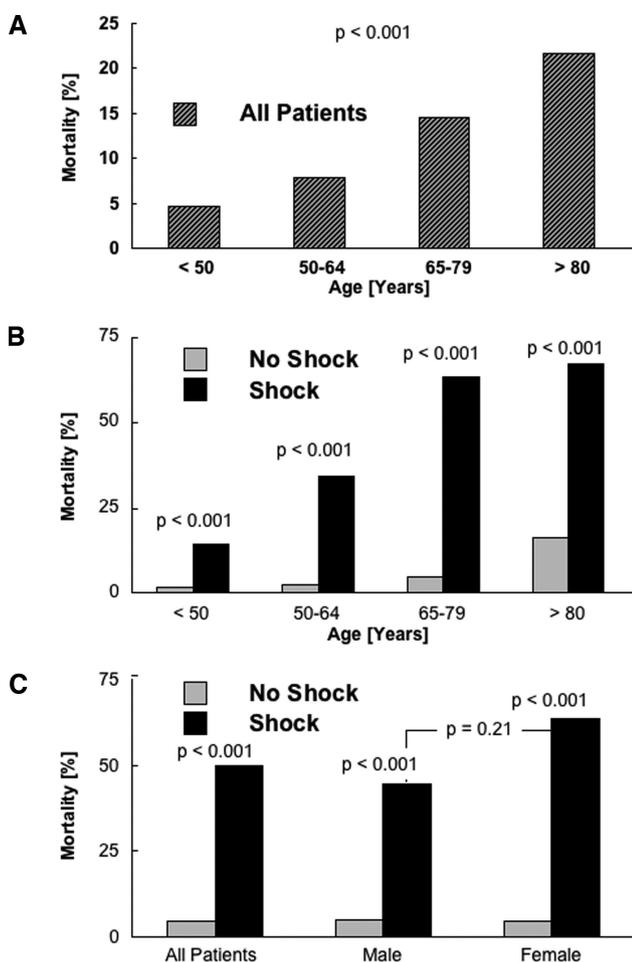
Figure 3. Mortality in KIM patients in 2006. A, Age-dependent mortality. B, Age-dependent mortality in patients presenting at first medical contact with and without cardiogenic shock. C, Mortality depending on gender and the presence or absence of cardiogenic shock at the time point of first medical contact.

and 6.9% had to be resuscitated. Patient characteristics are summarized in Table 1.

Patient Pathways Through the Medical System
Of all patients, 122 (24%) primarily presented at a hospital without a catheterization facility and were then transferred to a coronary intervention center; 55 (11%) presented at a coronary intervention center; 25 (5%) patients were contacted first by an EMS team, which transferred the patient to a district hospital without a catheterization laboratory; and 315 (60%) were first seen by an EMS team and transferred directly to a coronary intervention center. In 428 of 466 patients (91%) transferred to a coronary intervention center, the coronary intervention center was notified by phone to activate the catheterization laboratory team either by the EMS team or from another hospital before admission.

Correctness of Diagnosis
False-positive inclusions were defined as diagnosis of STEMI by the EMS doctor or admitting physician at a noncoronary intervention hospital and exclusion of STEMI by the specialist in the admitting coronary intervention center. False-positive ECG interpretation and patient inclusion into KIM

Table 1. Patient Demographics

No.	519
Men/women (%)	69/31
Age (mean±SD), years	63.4±13.9
Age between 65 and 79 years, %	67.6
Age 80 years and older, %	13.3
Cardiogenic shock, %	14.8
Major infarction vessel, %	
LAD	36.8 (n=174)
RD	3.2 (n=15)
LCX	13.3 (n=63)
RPLS	3.6 (n=17)
RCA	41.4 (n=195)
venous bypass graft	1.7 (n=7)

A lesion was regarded as significant when the stenosis occluded the vessel diameter by more than 70%.

LAD indicates left anterior descending artery; RD, ramus diagonalis; LCX, left circumflex artery; RPLS, ramus posterolateralis sinister; RCA, right coronary artery.

by EMS doctors and by admitting physicians in noncoronary intervention hospitals occurred in 6% and 5% of their patients, respectively.

Reaction Times
The reaction times are given in Table 2. The main time delay for most patients was the interval between the onset of symptoms and the first contact within the medical system, with a median symptom-to-contact time of 120 minutes.

Once the patient had been seen by a medical professional, median treatment times were all within the time limits recommended by international guidelines. Specifically, median phone-to-balloon time and door-to-balloon time were within the 90-minute range, which has been suggested as a discrimination criterion between primary interventional therapy and primary fibrinolysis by most guidelines. The achievement becomes evident when treatment times within KIM are compared with treatment times before its start. In 308 patients treated in the 2 biggest coronary care units in Cologne from

Table 2. Reaction Times (in Minutes)

Symptom-to-contact	120 (305)
Contact-to-balloon	92 (46)
Phone-to-balloon	70 (33)
Door-to-needle	26 (26)
Door-to-balloon	49 (30)

Reaction times are given as medians with the interquartile range in parentheses. Symptom-to-contact time means interval between onset of symptoms and first contact with a medical professional. Contact-to-balloon time means time between first contact with a medical profession and first coronary balloon inflation. Phone-to-balloon time is the interval between notification of the coronary intervention centre by the referring EMS doctor or by the referring district hospital and first coronary balloon inflation. Door-to-needle time is the time interval between arrival of a patient at the coronary intervention centre and puncture of the femoral artery. Door-to-balloon time is the time interval between arrival of the patient at the coronary intervention centre and first coronary balloon inflation.

Table 3. Mortality in STEMI Patients According to Risk Factors

	Yes, %	No, %	Level of Significance
Men	11.5		0.62*
Women	13.5		
Age ≥ 80 years	24.7	10.2	<0.001
Cardiogenic shock at primary contact	50.0	5.3	<0.001
Resuscitation by EMS	56.1	6.4	<0.001
Resuscitation at admission in coronary intervention center	65.7	7.7	<0.001
Mechanical ventilation at admission in coronary intervention center	57.6	5.1	<0.001

*Comparison of men and women.

January to June 2005, median door-to-needle time was 43 (49) minutes, and median door-to-balloon time was 72 (65) minutes. For patients treated in these coronary care units between January and June 2006, (ie, after the start of KIM), median door-to-needle time was 20 (22) minutes, and median door-to-balloon time was 42 (33) minutes. It has to be noted that there were a number of cases in which this goal for interventional treatment within 90 minutes was not achieved. However, 74.4% and 79.8% of patients were treated within a phone-to-balloon time and a door-to-balloon time, respectively, of <90 minutes.

When treatment times of the 5 intervention centers were compared, there were minor differences, with all centers lying within the requested time limits (Figure 2A, $P<0.001$). There were no significant differences in treatment times when the time periods within 2006 and by the end of 2005 were compared (Figure 2B, $P=0.33$; Figure 2C, $P=0.12$).

Intervention Rate and Results

As intended, coronary angiography rate was high. A total of 516 patients were admitted at a coronary intervention center and 479 of all patients (92.8%) underwent coronary angiography. Of these patients, 409 (85%) had an indication for immediate coronary angioplasty. The major infarction vessels are given in Table 1. Of all patients, 91.1% (n=407) presented with infarction-related stenoses (>80%) in one vessel, 6.8% (n=30) presented with stenoses in 2 vessels, and 1.1% (n=5) presented with stenoses in 3 vessels. Fifty patients required a second intervention, either at their infarction vessel (n=16) or in another vessel (n=34).

Seventy-six percent of patients with coronary angiography required stent implantation; 10% underwent coronary angioplasty without stent implantation; and 5% were transferred to coronary artery bypass graft surgery, either directly or after coronary angioplasty. In those undergoing coronary angioplasty, the success rate, defined as achievement of TIMI 3 flow, was 89%.

Death and Reinfarction

Two patients died in their district hospital without transfer to an intervention center and 61 patients died after admission to a coronary intervention center;the mortality rate was 12.1%. Ten patients (1.9%) experienced a reinfarction. Of 479

patients who underwent coronary angiography, mortality was 11.9%. For comparison, the mortality rate was analyzed for patients treated at the 2 biggest intervention centers of Cologne between January and June 2005, before the start of KIM. Mortality rate among 308 patients treated at the 2 major coronary intervention centers in Cologne was 10.4%. One year later, between January and June 2006, after the start of KIM, the mortality rate was 7.6% in these 2 centers.

Major determinants of mortality were old age and unstable circulatory stage at primary contact or admission to the intervention center. There was a significant trend of mortality increasing with age ($P<0.001$), with the mortality rate for patients at age ≥80 years being 6 times higher than that for patients <50 years of age (Figure 3). Also, mortality was significantly increased in patients with cardiogenic shock. Patients who were in shock (defined as either inotropic failure or cardiac arrest) at first medical contact had a mortality rate of 50%, whereas patients who were not shock had a mortality rate of 4.72%. Patients with inotropic failure (systolic blood pressure <100 mm Hg) had a mortality rate of 36.1%. Within this group, those without the need for resuscitation had a mortality rate of 16.9%, and those with need for resuscitation had a mortality rate of 59.2%. Patients with cardiac arrest (documented ventricular fibrillation) had a mortality rate of 55.9%. Risk factors for increased mortality are given in Table 1.

Secondary Preventive Medication at Discharge and Follow-Up

Secondary preventive medication was defined as prescription of β-blockers, angiotensin-converting enzyme inhibitors, aspirin, or statins at the time of hospital discharge. This criterion was met by 82.4% of patients who were directly discharged from a hospital with coronary intervention unit and by 79.2% of patients who were discharged from a hospital without a coronary intervention unit.

Discussion

KIM is the first attempt to implement PCI as obligatory therapy for all patients presenting with acute STEMI within a metropolitan European setting. The data of the KIM registry presented in this study provide evidence for the feasibility of recent US and European guidelines recommending PCI as first-line therapy for acute STEMI. The major findings are as follows:

- Combined efforts of a metropolitan EMS, district hospitals, and specialized cardiology units and implementation of coordinated standard operating procedures allow treatment of nearly all STEMI patients in a city with a population of 1 million citizens by primary PCI within a phone-to-balloon time of <90 minutes.
- ECG training and the use of 12-lead ECG by the EMS team provide sufficient competence for diagnosis of STEMI and initiation of treatment pathways.
- Despite all efforts, overall mortality remains high, which is due to a high number of patients being treated by PCI despite very old age and unstable circulatory state.

The present data go beyond a recent report presenting results of the Viennese STEMI Registry. In Vienna, the

metropolitan ambulance system cooperated with 5 interventional cardiology departments, guaranteeing that a catheterization laboratory was available 24 hours a day in ≥2 alternating places. The primary triage of patients to either thrombolysis or PCI was performed by the EMS physicians. Implementation of the guideline led to a marked increase in the percentage of patients receiving PCI as first-line therapy, finally leading to a decrease in in-hospital mortality from 16% to 9.5%.[9] The aim of KIM was to guarantee PCI in time as primary therapy for all STEMI patients within a city of 1 million citizens. As consequence, the Cologne EMS, all coronary intervention centers, and all regular hospitals within Cologne agreed to provide an infrastructure guaranteeing a contact-to-balloon and phone-to-balloon time of <90 minutes to every patient presenting with STEMI, 24 hours a day. Only 2 of 591 patients with STEMI were not transferred to a coronary intervention center; the majority of patients underwent coronary angiography and angioplasty. This supports the finding that the prevalence of normal coronary angiography in acute STEMI is below 3%.[10] As in Vienna, the KIM delay times were within the time limits requested by American Heart Association, the European Society of Cardiology, and national guidelines.[11,12] Thus, the consequent guideline implementation in a metropolitan area enables PCI as obligatory first-line therapy for STEMI.[13,14]

Recently, activation of the catheterization laboratory by EMS while the patient is on the way and staff arriving at the catheterization facility within 20 minutes after being paged have been named as major strategies leading to a decrease in treatment delay.[15] Data from the KIM registry confirm that this approach leads to short delay times and prompt coronary interventions. One of the most important innovations was triage responsibility of the EMS physician. KIM proves that activation of the catheterization team by EMS staff only rarely leads to "false alarm." Nearly all patients (93%) who were transferred to a coronary intervention center had an indication for emergency coronary angiography and intervention. Thus, EMS doctors equipped with 12-lead ECG develop sufficient diagnostic competence for handling the therapeutic triage in STEMI patients. The specificity of diagnosis based on prehospital 12-lead ECG as observed in this study is similar to that in an assessment of the US Agency for Healthcare Research and Quality, which calculated the specificity of prehospital 12-lead ECG-based diagnosis as 97%.[16] It was even higher than that in a recent report from San Diego in which specificity of ECG-based diagnosis was 78% in the hands of paramedics and 96% if ECG was interpreted by physicians after electronic transfer[17]

The number of patients included in KIM within 12 months was lower than expected. Based on data of the Monitoring Cardiovascular Disease (MONICA) trial obtained in the region around Augsburg, a city in southern Germany, it can be expected that there are 1800 patients with a STEMI per 1 million citizens per year.[18] Because the intention of the KIM organizers was to include every patient with a new STEMI, the achieved number of 561 patients in 2006 appears to be too low. Possible explanations are as follows: (1) the incidence of STEMI is lower than estimated; (2) many patients with STEMI do not contact the medical system; and (3) despite the

agreement for cooperation, a number of patients are not included in KIM and are not transferred from their primary hospitals to a coronary intervention center.

The hypothesis that patients might not reach a hospital or might not even get in touch with a medical professional is reflected by the threatening observation that the median time between onset of symptoms and first medical contact is 120 minutes. The impact of time delay until first medical contact on the increase in mortality has been characterized very well.[19] The long symptom-to-contact time is another argument in favor of PCI because thrombolysis is mainly efficient within the first 2 hours after the onset of symptoms.[6,20,21,22]

KIM did not lead to a major reduction in mortality. In fact, the mortality rate of 12.1% is higher than that in many other trials comparing thrombolysis and PCI for STEMI therapy.[10,20,23] One explanation is that a high number of patients presented with cardiogenic shock, defined as either patients who primarily survived cardiac arrest or patients with inotropic failure. These patients had a 10-fold increased risk of death compared with patients without shock, which was similar to a 25-fold increase in the risk of death for patients with cardiogenic shock in the Vienna STEMI registry.[9] More precisely, the mortality rate in patients with cardiac arrest was 56%. In patients with inotropic failure, the mortality rate was 39%. In contrast, in patients without cardiac arrest or inotropic failure, the mortality rate was 5%. This confirms earlier data collected by a group of German hospital cardiologists in 4815 STEMI patients who demonstrated that cardiogenic shock led to an increase in in-hospital mortality rate from 4% to 40% and was a more important determinant of mortality than in-hospital treatment time.[24] Another reason might be the high percentage of patients of older age in the KIM registry. In the Maximal Individual Therapy of Acute Myocardial Infarction (MITRA PLUS) registry comparing the effects of thrombolysis and PCI in STEMI patients >70 years of age, the mortality rates were 17.8% and 12.5%, respectively. In KIM, the mortality rate for patients ≥80 years of age was 24.6% in contrast to a mortality rate of 10.2% for patients <80 years of age.[25] The number of patients presenting with cardiogenic shock or at very old age increased between the period before KIM and after initiation of KIM; for example, in the 2 major coronary intervention centers, 8% of patients were ≥80 years of age, and 9.7% of all patients presented in cardiogenic shock from January to June 2006, before the start of KIM. In contrast, in the first half of 2006, 13% of patients were ≥80 years of age, and 15.2% presented in cardiogenic shock. In this context, it can be speculated whether the triage rules in KIM allow more circulatory unstable patients to arrive and to be treated in a catheterization laboratory. This might lead to an increase in mortality. On the other hand, high-risk patients benefit most from PCI rather than thrombolytic therapy. In this context, a retrospective analysis of the Danish Multicenter Randomized Study on Fibrinolytic Therapy Versus Acute Coronary Angioplasty in Acute Myocardial Infarction (DANAMI-2) trial showed that in high-risk STEMI patients with a TIMI risk score ≥5, PCI lead to a reduction in mortality to 25.3% compared with 36.2% in patients receiving thrombolysis.[26]

There are many limitations of this study. Some concerns have been mentioned already. There is no control for false-negative diagnoses leading to an exclusion of patients because of ECG misdiagnosis. Thus, there is no evaluation of how many patients with STEMI were missed despite contacting the medical system. Also, so far, there have been no regular audits of the participating hospitals controlling for patients diagnosed as suffering from STEMI but not included in KIM. However, comparing the KIM data of 2 randomly chosen KIM hospitals with their own International Statistical Classification of Disease and Related Health Problems (ICD) code statistics makes us believe that the presented data do reflect the reality in Cologne in 2006. Treatment data were provided by the treating EMS team and hospital physicians, and there might have been a trend to artificially improve their own treatment results. Finally, the comparison between treatment parameters before and after the initiation of KIM is difficult, because data for the time before KIM have been generated retrospectively.

In conclusion, KIM demonstrates that PCI can be offered as a preferred and obligatory therapy for patients with acute STEMI. KIM proves that if recent recommendations for the organization of a STEMI network are put into practice—especially the implementation of prehospital ECG diagnosis, direct transfer to a coronary intervention center, and activation of the catheterization laboratory staff by the EMS physician—treatment times are within the limits requested in the actual guidelines for the primary use of PCI for the treatment of myocardial infarction. The widespread use of primary PCI leads to favorable treatment results for the majority of patients.

Disclosures

None.

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CLINICAL PERSPECTIVE

International guidelines suggest acute percutaneous coronary intervention as the preferred therapy for acute ST-segment–elevation myocardial infarction (STEMI). So far, there are few reports on the feasibility and results of implementation of these guidelines. The Cologne Infarction Model is an attempt to analyze the feasibility of guideline implementation and its clinical impact for STEMI patients. The Cologne Infarction Model was performed in Cologne, a German city with >1 million citizens, 5 catheterization facilities with 24-hour availability, and 11 primary care hospitals. The emergency medical service is centrally organized. Twelve-lead ECG is available for all emergency medical service teams. Thus, Cologne provides optimal premises for guideline implementation. Partners guaranteed direct transfer of patients with STEMI to a catheterization laboratory, with emergency medical service teams being in charge of treatment triage and primary care hospitals renouncing routine first treatment of the patients within their district. The analysis of all patient clinical pathways in 2006 supports the feasibility of guideline-adherent treatment of STEMI. The majority of patients were transferred directly to a coronary care unit. Nearly all patients arriving at a catheterization laboratory were announced by phone, which allowed median treatment times to be well within the guideline limits. ECG competence of emergency medical service and district hospitals was very high, resulting in most patients receiving angiography and acute coronary intervention. Interestingly, guideline implementation did not lead to a major drop in mortality. This interesting finding could be explained by inclusion of a higher number of patients with high-risk features in response to easy access to catheterization facilities in this treatment pathway.

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