

# Resting Magnetocardiography Predicts 3-Year Mortality in Patients Presenting with Acute Chest Pain without ST Segment Elevation

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**Objective:** Magnetocardiography (MCG) as a noninvasive, noncontact and risk-free diagnostic method predicts ischemic coronary artery disease (CAD) in patients with acute chest pain at admission with high accuracy. However, it remains unclear whether MCG findings can add prognostic information.

**Method:** A cohort of 402 consecutive patients presenting at the intensive care unit (ICU) with acute chest pain without ST segment elevation (NSTEMI) were included in a prospective registry. In order to prove the prognostic value of MCG a head-to-head comparison of the admission MCG, ECG, TnI, and ECHO tests was made.

**Results:** In 43 patients (10.7%) the MCG could not be analyzed due to insufficient signal-to-noise ratio. Complete follow-up over a period of up to 3 years was obtained in 355 out of the 359 patients (98.9%). Age at admission was  $67.2 \pm 10.3$  years, 59.7% males. In the group of patients with an abnormal MCG at admission, 43 out of 249 patients (17.3%) died in the follow-up period, while in the group of patients with a normal MCG at admission only 4 out of 106 patients died (3.77%). The relative risk was 4.58 (95% confidence intervals: 1.68–12.42). A multivariate regression analysis revealed the highest mortality risk for patients with diabetes mellitus and an abnormal MCG at admission (RR = 18.0; 95% CI: 2.49–133.3).

**Conclusion:** Resting MCG at hospital admission predicts 3-year mortality in patients presenting with acute chest pain without ST segment elevation in the ECG. MCG seems to be valuable in identifying chest pain patients at highest risk. *Ann Noninvasive Electrocardiol* 2008;13(2):171–179

magnetocardiography; coronary artery disease; chest pain; mortality; prognosis

The prognosis of future coronary events or even of death in patients with coronary artery disease (CAD) represents a significant and never-ending challenge in spite of the fact that many risk factors predicting future events have been identified, and risk stratification schemes have been proposed.<sup>1–3</sup> About a quarter of serious cardiovascular events remain unexplained even in an environment of multifactorial risk stratification and modification. These may be the result of a complex interaction of plaque morphology, disturbed endothelial function, and thrombogenesis due to the chronic inflammatory and the recurrent nature of atherosclerotic vascular diseases.<sup>4–6</sup> Patients with acute

coronary syndromes (ACS) without ST segment elevation (NSTEMI) are a heterogeneous group with varying short- and long-term prognoses.<sup>4,7</sup> Therefore, the early recognition of patients at high risk for future mortality or morbidity at the time of admission to the hospital or initial diagnosis is a prerequisite for optimal triage and therapeutic decisions including early invasive strategies. In addition, early identification of these high-risk patients would offer the opportunity for closer, more frequent clinical evaluation in this patient population, thereby apportioning and justifying increased monitoring for the higher-risk patient in the outpatient setting.

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Clinical examination, including the patient's individual medical history, electrocardiographic (ECG) recordings, and measurements of biomarkers are to date the most important tools for risk assessment.<sup>1-3</sup> The resting ECG is a key in the examination of patients with suspected ACS. ST segment elevation myocardial infarction (STEMI) and new bundle branch block in the appropriate clinical setting clearly represent the highest morbidity and mortality risk class in the ACS population. Transient episodes of ST segment deviation (elevation and depression) and dynamic T wave changes in the appropriate clinical setting represent ischemic events and also have an impact on the prognosis of future coronary events.<sup>7-9</sup> Nevertheless, most ischemic episodes are not definitively diagnosed or even not detectable by conventional ECG.<sup>7</sup> In these, and in other situations, elevations of cardiac troponin is currently utilized not only as a marker of myonecrosis, but also as a predictor of adverse outcome in patients with ACS.<sup>1,7,10,11</sup> In addition, a common diagnostic procedure in patients presenting to the emergency department with suspected ACS includes a rest echocardiogram, performed prior to or shortly after hospitalization, evaluating for wall motion abnormalities. The presence of wall motion abnormalities on presentation suggests a higher future risk of morbidity and mortality for the patient.<sup>12</sup>

Magnetocardiography (MCG) is a noncontact, noninvasive, risk- and radiation-free method allowing body surface recording of the magnetic fields generated by the electrical activity of the heart.<sup>13,14</sup> Recently, it could be shown by our group that the magnetocardiogram in patients with acute chest pain without ST elevation has a high positive predictive value for CAD comparable to troponin I (TnI), but, at the same time, an almost three-fold higher negative predictive value.<sup>15</sup> However, up to date it has not been clear whether MCG can improve the prognostic estimate of long-term risk in these patients over that using present-day standard diagnostic techniques. The former study<sup>15</sup> began as a prospective registry of patients presenting with suspected ACS in the emergency department of a general hospital. Up to now a cohort of 402 patients has been included. It was the goal of the present analysis to investigate the prognostic value of MCG in these patients after a follow-up of 3 years and to compare the results with that of standard diagnostic parameters.

## METHODS

### Study Design

The single-center registry study was conducted as a prospective, intraindividual, comparative examination of different diagnostic procedures performed on patients after their admission to the intensive care unit (ICU) of the Cardiology Division, Medical Clinic I at Hoyerswerda Hospital, Hoyerswerda, Germany. All patients were 18 years of age or older and were referred either by personal physicians in private outpatient clinics, emergency physicians at the outpatient rescue service, or the hospital emergency department. The registry included only patients in whom the criteria for group 2 according to the European Society of Cardiology guidelines for patients with ACS were applicable and coronary angiography (CA) was indicated and performed within 36 hours after admission to the ICU.<sup>7,15</sup> In general, this was the case in patients who suffered from recurrent angina pectoris despite optimal medical treatment and/or had or developed clear pathologic changes in subsequent ECG, TnI, or ECHO examinations, respectively. Patients with acute myocardial infarction, who were unambiguously diagnosed with a 12-lead surface ECG, hemodynamically unstable patients, and patients who refused entry into the registry were excluded. In addition, patients with a reduced left ventricular function (LVEF < 40%) determined by ECHO were excluded from the registry due to the fact that this finding is an unfavorable prognostic indicator in itself (Fig. 1). Patients with left or right bundle branch block were explicitly not excluded. The patients underwent standard clinical evaluation immediately after admission including history and physical examination, laboratory testing, resting ECG, and resting echocardiography (ECHO). Additionally, a magnetocardiogram was performed. The ECG was recorded closely before the MCG with the patient lying on the MCG table, which is located in the ICU. An ECG was defined as positive if a ST segment depression was greater than 1 mm (0.1 mV) in two or more contiguous leads, or inverted T waves (>1 mm) in leads with predominant R waves occurred. An ECHO was defined as positive if wall motion abnormalities were found. A TnI was defined as positive above the cutoff point of <0.5 ng/mL (Access AccuTnI<sup>TM</sup>, Beckman-Coulter, Krefeld, Germany). Angiograms

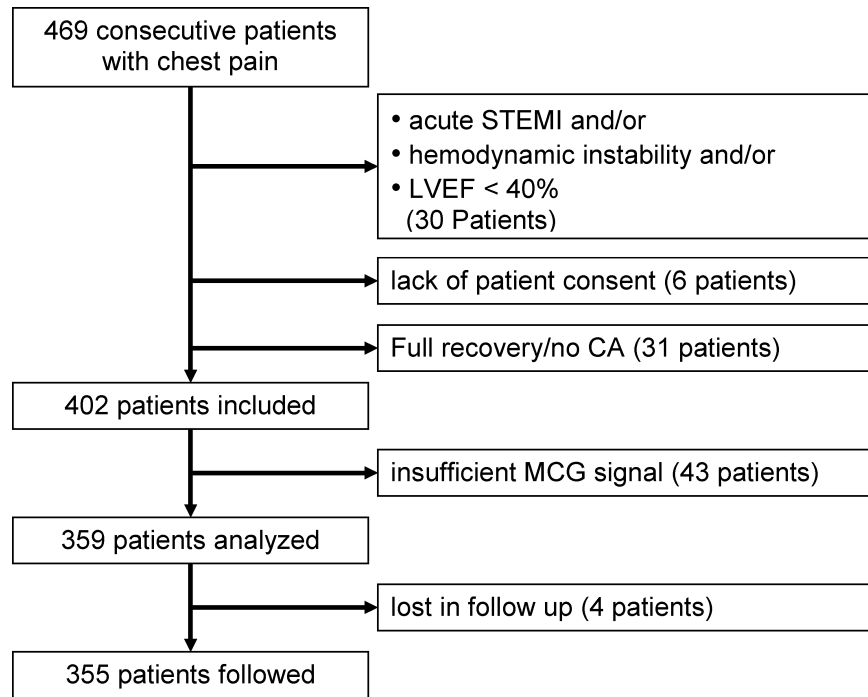


Figure 1. Flow diagram of patient inclusion/exclusion.

were defined as positive if at least one coronary artery branch of first or secondary order revealed a 50% or greater degree of stenosis.<sup>16</sup> Stenosis or occlusion of vessels was not regarded as positive if the corresponding bypass graft was intact.

The results of the MCG analysis, the laboratory testing, ECG, and echocardiographic examinations as well as the CA were entered into a database and further processed for independent statistical analysis by the Institute for Heart and Circulation Research, Hoyerswerda, Germany. In order to define the prognostic value of MCG a head-to-head comparison of the admission MCG, ECG, TnI, and ECHO tests was made. The study complies with the Declaration of Helsinki. The locally appointed ethics committee of the "Chamber of Physicians of the state of Saxony" approved the study, and informed consent was obtained from all patients.

### Magnetocardiography

The magnetocardiographic examination was carried out with the 9-channel mapping system "CMI 2409" (CardioMag Imaging, Inc., Schenectady, NY, USA). Nine DC-SQUID sensors are coupled to second-order axial gradiometers, which measure local magnetic field components directly above and

close to the torso of the patient. Details of the magnetocardiograph used in this study are published elsewhere.<sup>15,17</sup>

The MCG data were analyzed in a two-step fashion. First, they were displayed in scalar form with QRS complexes, ST segments, and T waves. This enables the choice of specific areas, which were represented in the form of magnetic field maps. With these maps a series of parameters then were calculated. Criteria for ischemia were exclusively analyzed during the time interval between the beginning of the T wave ( $T_{\text{beg}}$ ) and the maximum of the T wave ( $T_{\text{max}}$ ). Four parameters were defined, from which at least one parameter had to be abnormal for the MCG to be considered abnormal: the direction of the vector (from plus pole to minus pole), the change in the angle of this vector, the change in the distance between plus and minus poles, and the change in the ratio of the pole strengths. Rapid changes in these parameters in a time interval of 30 ms in the MCG interval between  $T_{\text{beg}}$  and  $T_{\text{max}}$  were characteristic of CAD. The following cutoff values were found of optimal sensitivity and specificity for the detection of CAD in patients with acute chest pain without ST segment elevation.<sup>17</sup> The same diagnostic criteria were applied for the purpose of this study:

- P1: The direction of the main vector lies between  $-20^\circ$  and  $+110^\circ$  (in case of left bundle branch block this vector always lies between  $-20^\circ$  and  $+110^\circ$ , so that this parameter could not be used for the determination of ischemia). If the direction of the current vector lies between  $+110^\circ$  and  $-20^\circ$  then
- P2: a change in the angle of the main vector of more than 45 degrees within a time interval of 30 ms between  $T_{\text{beg}}$  and  $T_{\text{max}}$ , or
- P3: a change in the distance separating the plus and minus poles of more than 20 mm within a time interval of 30 ms between  $T_{\text{beg}}$  and  $T_{\text{max}}$ , or
- P4: a change in the ratio of the plus and minus pole field strengths of more than 0.3 within a time interval of 30 ms between  $T_{\text{beg}}$  and  $T_{\text{max}}$ .

Patients whose data were uninterpretable due to the presence of signal confounding ICDs, pacemakers, bypass clips, nonremovable dentures, or insufficient signal-to-noise ratio were excluded from further analysis.<sup>15</sup>

### Statistics

Data are reported as mean value  $\pm$  standard deviation for continuous variables, or as percentages for categorical variables. Survival according to Kaplan-Meier was calculated grouped for MCG, ECG, TnI, and echocardiogram using univariate analysis. Differences in survival were assessed by the use of a log-rank test. In a second analysis (multivariate regression analysis) it was evaluated which parameter out of MCG, ECG, TnI, ECHO, age, sex, diabetes mellitus, hypertension, hyperlipidemia, smoking, or body mass index (BMI) correlates with long-term mortality.

Finally, these parameters—on the basis of their correlation with subsequent mortality—were stratified to identify the groups of patients with the highest mortality risk.

## RESULTS

Between April 2002 and November 2003 a total of 469 consecutive patients with acute chest pain were referred to the ICU at the Cardiology Division. Thirty patients were excluded from the registry due to underlying acute ST-elevation myocardial infarction unambiguously diagnosed by means of 12-lead surface ECG, and/or hemodynamic instability and/or reduced left ventricular function

(LVEF  $<$  40%). Six patients refused to enter into the registry, 31 patients fully recovered in the early course of their admission with a normal ECG and ECHO findings and without elevation of TnI, so that urgent CA was not indicated. Thus, 402 patients were included in the prospective analysis of the registry, of which the MCG could not be analyzed in 43 patients (10.7%) due to the presence of signal confounding ICDs, pacemakers, bypass clips, nonremovable dentures, or insufficient signal-to-noise ratio. Therefore, 359 patients met all inclusion and exclusion criteria for complete analysis and follow-up in the registry. Complete follow-up over a period of up to 3 years was obtained in 355 out of the 359 patients (Fig. 1). Thus, the percentage of patients lost to follow-up was barely 1.1%.

Age at admission was  $67.2 \pm 10.3$  years, 59.7% males. Ninety-three patients had diabetes mellitus, 222 arterial hypertension, and 109 hyperlipidemia. Forty-two patients smoked up to the time of their admission, 123 had given up smoking, and 146 had never smoked. The BMI was  $28.1 \pm 4.5$ . Multivessel CAD was present in 46.9%. 28 patients had already suffered a myocardial infarction. Coronary stents were already implanted in 56 patients, while CABG had been performed in 22 others. 45 patients had to be transferred urgently for bypass surgery after CA. One hundred sixteen patients received at least one stent, in 89 procedures a GPIIb/IIIa-blocker was used, and during three of these procedures an intraaortic balloon pump was applied.

An abnormal admission MCG meeting criteria for ischemia was observed in 70.4% of the patients, while only 28.8% had an abnormal ECG (37 patients had either a left or a right bundle branch block, therefore, their ECGs could not be evaluated with respect to the diagnosis of ischemia), 46.4% revealed a pathological ECHO, and 32.1% of the patients had elevated TnI values. Table 1 summarizes the univariate prognostic significance of MCG taken on patient admission compared with other standard diagnostic tests: Of the patients with an abnormal MCG, 17.3% died in the follow-up period (on average within  $9.6 \pm 7.0$  months), while only 3.77% of the patients with a physiologic MCG died (on average within  $7.5 \pm 7.1$  months). Therefore, the relative risk of death is significantly increased in 3 years following an abnormal MCG (Fig. 2). The cumulative risk of dying during the following 3 years after an abnormal ECG was not increased in this cohort of patients although there

**Table 1.** Relative Risk of Death within a 95% Confidence Interval (95% CI) during 3 Years of Follow-Up (Univariate Analysis)

Test	Category	n	Death	Relative Risk	95% CI	P -Value*
MCG (n = 355)	Physiologic	106	4	4.58	1.68–12.42	0.0003
	Pathologic	249	43			
ECG† (318)	Physiologic	228	24	1.69	0.94–3.03	0.0572
	Pathologic	90	16			
ECHO‡ (n = 349)	Physiologic	188	20	1.58	0.92–2.70	0.0993
	Pathologic	161	27			
TnI§ (n = 354)	Not elevated	243	22	2.48	1.47–4.21	0.0005
	Elevated	111	25			

\*Log-rank (Mantel-Cox) test.

†ECG in 37 patients was not evaluable due to a left- or right-bundle branch block.

‡In six patients ECHO was not performed.

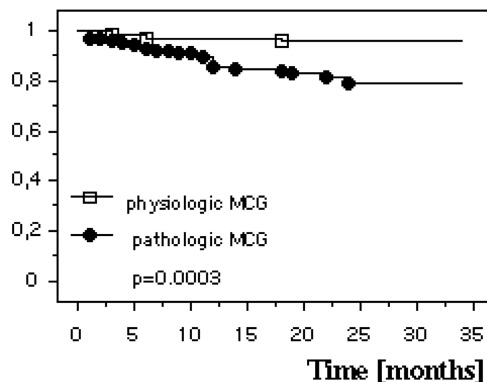
§One clotted blood sample, testing impossible.

is a tendency to die more frequently compared with a normal ECG (17.8% vs 10.5%).

Patients presenting with wall motion abnormalities in the ECHO at admission do not have an increased cumulative risk of death compared to those with a normal ECHO finding (16.8% vs 10.6%). In case of an elevated TnI on admission the relative risk of death is significantly increased, on average within  $11.3 \pm 7.2$  months in 22.5% of the patients, compared to those with normal values

(Fig. 3). The relative risk for known cardiovascular risk factors like diabetes mellitus, hypertension, hyperlipidemia, advanced age, male gender, and smoking in the present patient population is summarized in Table 2. Using a multivariate logistical regression analysis it was studied which of these variables correlate significantly with mortality. These turned out to be the MCG ( $P = 0.0033$ ), the presence of diabetes mellitus ( $P = 0.0105$ ) as well as an elevated TnI ( $P = 0.0056$ ). All other variables in this model had no effect on mortality. Further analysis revealed which combination of these three variables showed the highest mortality risk: In the 75 patients with a normal MCG without the presence of diabetes mellitus only one died during

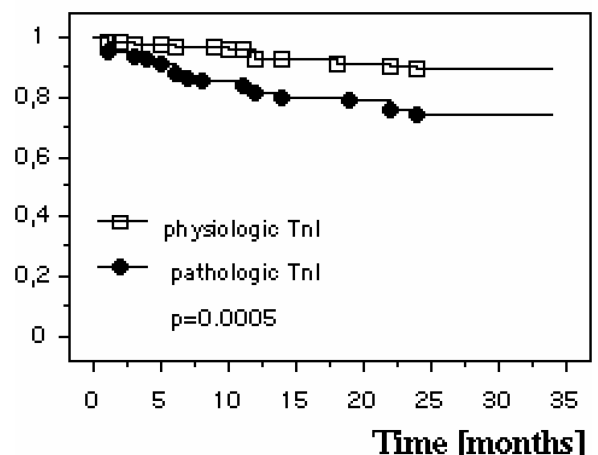
**Cumulative Survival**



Time [months]	0	5	10	15	20	25	30	34
<b>MCG pathologic</b>								
censored	0	14	35	50	87	128	175	206
death	0	14	22	35	37	43	43	43
at risk	249	221	192	164	125	78	31	0
<b>MCG physiologic</b>								
censored	0	4	7	11	28	59	82	102
death	0	2	3	3	4	4	4	4
at risk	106	100	96	92	74	43	20	0

**Figure 2.** Kaplan-Meier 3-year survival plot for patients with normal and pathologic MCG.

**Cumulative Survival**



**Figure 3.** Kaplan-Meier 3-year survival plot for patients with normal and elevated TnI values.

**Table 2.** Relative Risk of Death due to Cardiovascular Risk Factors within a 95% Confidence Interval (95% CI) during 3 Years of Follow-up

CRF	Category	N	Death	Relative Risk	95% CI	P Value
DM	Yes	104	21	1.99	1.17–3.39	0.0057
	No	246	25			
Hyp	Yes	250	32	0.92	0.51–1.66	0.8167
	No	101	14			
HLP	Yes	124	12	0.64	0.34–1.19	0.1306
	No	224	34			
Age > 65	Yes	209	36	2.45	1.25–4.77	0.0061
	No	142	10			
Sex	M	184	24	0.80	0.46–1.36	0.5532
	F	128	21			
Smoking	Yes	44	5	0.76	0.32–1.81	0.5115
	No	266	40			

CRF = cardiovascular risk factor; DM = diabetes mellitus; Hyp = arterial hypertension; HLP = hyperlipidemia.

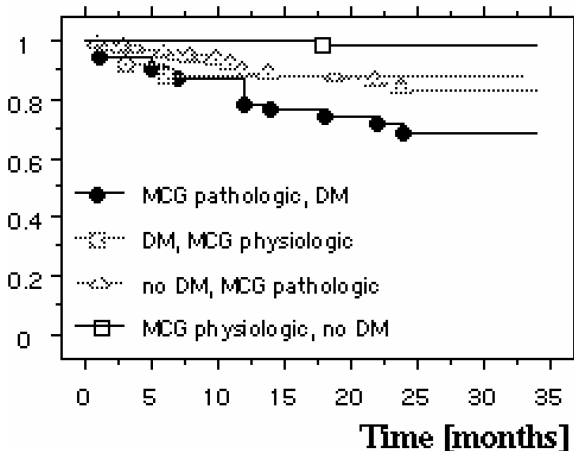
follow-up, whereas 18 of 75 patients died who had both diabetes mellitus and an abnormal MCG (n = 75 in both groups; P = 0.0005). In this population there is a relative risk of death of 18.0 (95% CI: 2.49–133.3) (Fig. 4). Comparable results were also found with a pathological MCG and simultaneously elevated TnI. Three out of 74 patients with both a normal TnI and a normal MCG died, while 24 of the 80 patients with elevated TnI and an abnormal MCG died during follow-up (P = 0.0002), a relative risk of 7.4 (95% CI: 2.32–23.5) (Fig. 5). Both, a normal TnI and no diabetes mellitus were found in 172 patients of which 13 died during follow-up, while 13 of the 35 patients with an elevated

TnI plus diabetes mellitus died (P = 0.0002), resulting in a relative risk of 3.99 (95% CI: 1.25–7.86) (Fig. 6).

### DISCUSSION

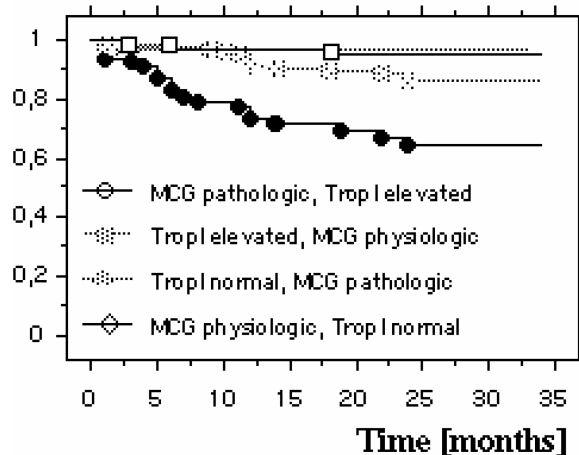
There is still need for a safe and simple noninvasive diagnostic procedure to separate patients with acute chest pain due to CAD from the large group of patients with thoracic complaints of noncardiac origin. The present work is based on a former study in which it could be shown that MCG provides a noninvasive, noncontact, radiation- and risk-free method, which can diagnose CAD with high accuracy in patients with acute chest pain without

**Cumulative Survival**

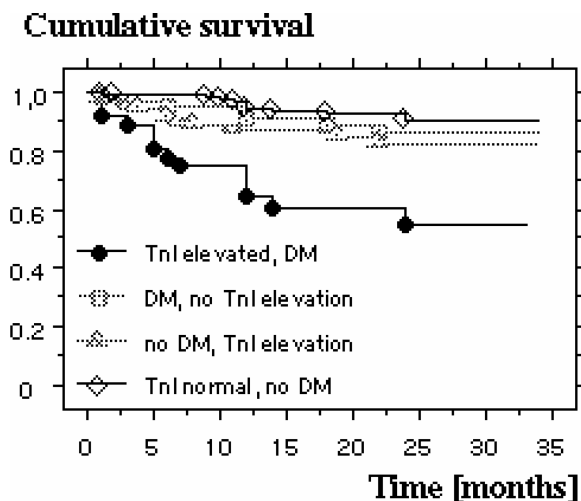


**Figure 4.** Kaplan-Meier 3-year survival plot showing dependency of MCG and diabetes mellitus.

**Cumulative Survival**



**Figure 5.** Kaplan-Meier 3-year survival plot showing dependency of MCG and TnI.



**Figure 6.** Kaplan-Meier 3-year survival plot showing dependence on TnI and diabetes mellitus.

ST-segment elevation.<sup>15</sup> With this technique the conclusion about heart muscle ischemia can be drawn from quantitative parameters of high temporal resolution derived from magnetographic maps which display the entire course of de- and repolarization of the heart. In terms of patient burden and diagnostic accuracy MCG appears to be superior compared to standard diagnostic procedures such as exercise treadmill, stress echo, or nuclear perfusion imaging.<sup>15,17,18</sup>

Our former study started as a registry of consecutive patients in which, up to now, 402 have been included and 359 patients met all inclusion and exclusion criteria for analysis. From the derived data the question about the predictive value of MCG in terms of mortality can be answered as follows: The relative risk of dying in the course of a 3-year follow-up period was, among four different diagnostic procedures, best predicted by MCG (RR = 4.41) followed by TnI values (RR = 2.52), while wall motion abnormalities on ECHO as well as an abnormal ECG offered very little or no prognostic value. It must be kept in mind that all examinations were conducted during patient admission and prior to CA or any optimal therapy based thereon. Therefore, the previous study is confirmed by the present data with respect to the negative predictive value of MCG of 84.8%, which was more than twice as high as that of the other methods (ECG: 27.4%; ECHO: 31.4%; TnI: 31.7%).<sup>15</sup> Only 3.77% of the patients with a normal MCG died in the course of the 3 years following their discharge. This percentage

was significantly higher for the other three methods: normal ECG: 10.5%; normal ECHO: 11.0%; negative TnI: 9.0%. Hence, it seems that MCG can correctly identify those patients with chest pain of noncardiac origin, and in addition, those with a good long-term prognosis. In addition, the results of a multivariate regression analysis showed that an abnormal magnetocardiogram, the presence of diabetes mellitus, as well as elevated TnI values, independent of each other, correlated with mortality over the follow-up period. A significantly elevated mortality risk can be attributed to patients with diabetes mellitus suffering from acute chest pain combined with an abnormal MCG on admission. These patients have a 18-fold elevated relative risk of dying compared with those patients without these two factors. Patients having the combination of an abnormal MCG and elevated TnI values on admission revealed a seven-fold increased risk of death, and for patients with the combination of diabetes mellitus and elevated TnI the mortality is four times higher than without those risk factors. All other conventional cardiovascular risk factors played no role in this model for 3-year prognosis.

The prognosis of clinical presentations of acute chest pain in real-life patient cohorts has not been well documented. Despite a 50% decrease of population, which took place in this geographic region at the extreme east of Germany in the years after the collapse of the Germany Democratic Republic due to migration of the younger people toward the western parts of the country, the mean age of the population in our registry seems to be in the range of comparable ones.<sup>3,19,20</sup> Nevertheless, the 13% 3-year mortality observed in the study population is relatively low compared to those studies. From the Global Registry of Acute Coronary Events (GRACE), Tang et al. reported a mortality of 25.0% at 3 years, and of 39.2% at 4 years, including patients with STEMI, NSTEMI, and unstable angina.<sup>3</sup> In the study of Nikus et al., the mortality in patients with NSTEMI or unstable angina after a median follow-up of 10 months was 27% and 12%, respectively.<sup>19</sup> After a median follow-up of 26 months in patients with non-ST elevation chest pain, Sanchis et al. reported a mortality of 5–14%, depending on risk score stratification and the presence of ST segment deviations and/or elevated troponin levels.<sup>20</sup> Interestingly, the aforementioned studies<sup>3,19,20</sup> and ours similarly identify age and diabetes mellitus as independent risk factors of death, whereas troponin

was of predictive value only in the studies of Sanchis<sup>20</sup> and ourselves.

The low mortality in our study population might be a consequence of a consistent therapy beginning at the time of diagnosis and continued after discharge from the hospital. In this region practically all patients with acute chest pain or ACS are admitted or readmitted to Hoyerswerda Hospital and the family practitioners around in general comply with our treatment recommendations. That is precisely why those patients might benefit from a fast diagnosis and an accurate risk stratification.<sup>21,22</sup> These circumstances may further underline the meaning of this study as a "cross-sectional real world" registry.

We conclude that MCG is a noninvasive technique with negligible burden to the patients, which can—possibly with the adjunctive knowledge of troponin values—accurately stratify patients with acute chest pain without ST-segment elevation at high risk and therefore require special diagnostic and therapeutic attention. Consequently, MCG meets the recommendations of the European Society for Cardiology, which demands the earliest possible risk assessment at the time of the initial diagnosis.

Additionally, future studies examining the benefit of routine MCG screening in patients with known CAD should be conducted. These studies would define the role this sensitive modality could play in early identification of subclinical ischemia in these high-risk patients, allowing clinicians an opportunity to intervene medically or surgically prior to the development of significant cardiac events or even death.

### Limitations of the Study

The magnetocardiographic examinations could not be analyzed in 10.7% of the patients due to the presence of signal confounding artifacts, or insufficient signal-to-noise ratio. This is partly due to the magnetically unshielded environment in which the examinations took place. Therefore, magnetic shielding seems to be mandatory for routine clinical use of MCG.

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