Predictors of survival in patients with acute coronary syndrome undergoing percutaneous coronary intervention of unprotected left main coronary artery stenosis

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Abstract
Objective: Aim of this study was to investigate predictors of survival in unstable patients with high SYNTAX-1-score.
Background: In significant unprotected left main coronary artery (ULMCA) stenosis, treatment options include percutaneous coronary intervention (PCI) and coronary artery bypass graft (CABG). While CABG is recommended for stable patients with ULMCA stenosis and a SYNTAX-1-score > 32, PCI may be preferable in unstable or high operative risk patients.
Methods: Retrospective single-center all-comers registry study.
Results: A total of 142 patients underwent ULMCA-PCI (~72.9 years, 23.2% females, 54.2% survival in 2-year follow-up), 84 of whom had a SYNTAX-1 > 32 (37.4 ± 12.8). Patients in the high-SYNTAX-1-group (score > 32) were more often in an acute condition compared to low-SYNTAX-2-group (score ≤ 32) including acute myocardial infarction (76.2% vs. 57.4%, p = .024), cardiogenic shock (48.2% vs. 14.8%, p = .001), or need for mechanical support (36.1% vs. 11.1%, p = .001). Survival was predicted by the acute condition including cardiogenic shock (OR 0.06 and 0.05) and myocardial infarction (OR 0.03 and 0.34) in both groups. Performance of the SYNTAX-1-score was limited in our patient collective in both groups (c-index 0.65 vs. 0.63) while SYNTAX-2-PCI-score performed better (c-index 0.67 vs. 0.67). EuroScore II had the best discriminative ability (c-index 0.87 vs. 0.78).
Conclusions: The majority of patients undergoing ULMCA-PCI presented in acute conditions with high SYNTAX-1-score, and is therefore underrepresented in clinical trials. Prognosis was best predicted by the acute condition and the EuroScore II. These data suggest that therapy in unstable patients should be guided by clinical condition over the anatomical SYNTAX-1-score.

Keywords
ACS, coronary disease, outcome, PCI, survival, ULMCA

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1 | INTRODUCTION

Stenosis of the unprotected left main coronary artery (ULMCA) is one of the most challenging conditions of coronary artery disease (CAD). Treatment strategies of left main stenosis in stable patients at low operative risk are well discussed in most recent ESC/EACTS guidelines. In these patients, the revascularization strategy using either coronary artery bypass graft surgery (CABG) or percutaneous coronary intervention (PCI) is guided by CAD severity as quantified by the SYNTAX-1-score.

In stable patients, complexity of CAD accompanying the stenotic ULMCA is a key predictor of outcome. Data from large randomized trials suggest that in patients with a SYNTAX-1-score below 22, PCI and CABG perform equally well. Current guidelines therefore indicate that PCI is an appropriate alternative to CABG in ULMCA stenosis with low to intermediate anatomical complexity. In patients with high SYNTAX-1-score (>32), however, current guidelines recommend CABG over PCI. This recommendation is based on data derived from patients who could have been randomized to undergo either PCI or CABG. The number of patients with high complexity of CAD studied in randomized controlled trials is low due to exclusion criteria and difficult randomization of unstable patients. The risk estimates and confidence intervals are therefore imprecise, but suggest a trend toward better survival with CABG. Therefore, PCI in stable patients with a SYNTAX-1-score > 32 cannot be endorsed by current guidelines as reflected by a class III recommendation.

Importantly, not all patients can be triaged exclusively by coronary artery anatomy. Acute ST-segment elevation myocardial infarction (STEMI) is an indication for percutaneous coronary intervention (PCI) if the lesion is amendable to stenting, disregarding the SYNTAX-1-score. Furthermore, presentation in cardiogenic shock due to STEMI or NSTE-ACS is an indication for PCI in case of a culprit lesion amenable to PCI. Other reasons for performing PCI over CABG in patients with a left main culprit lesion include an expected high risk of general anesthesia in patients with end stage pulmonary or renal disease. Comorbidities will increase as consequence of the demographic change. Furthermore, registries report an increased incidence in cardiogenic shock. This extrapolates for an increase in patient numbers with indication for an acute revascularization by PCI despite high SYNTAX-1-score.

### TABLE 1

| Characteristics          | All patients | SYNTAX ≤ 32 | SYNTAX > 32 | p-value |
|--------------------------|--------------|-------------|-------------|---------|
| Patients                 | 142          | 54          | 84          | 2 versus 3 |
| Age (years)              | 72.9 ± 11.2  | 73.4 ± 10.8 | 72.4 ± 11.5 | n.s.    |
| Female gender            | 23.2% (33)   | 20.4% (11)  | 26.2% (22)  | n.s.    |
| Arterial hypertension    | 88.7% (126)  | 96.3% (52)  | 83.3% (70)  | n.s.    |
| Current smoker           | 19.0% (27)   | 16.7% (9)   | 20.2% (17)  | n.s.    |
| Pack years               | 32.9 ± 24.3  | 29.3 ± 27.3 | 37.3 ± 20.9 | n.s.    |
| Diabetes mellitus        | 28.9% (41)   | 25.9% (14)  | 32.1% (27)  | n.s.    |
| Obesity                  | 40.8% (58)   | 46.3% (25)  | 38.1% (32)  | n.s.    |
| Chronic kidney disease   | 38.0% (54)   | 31.5% (17)  | 42.9% (36)  | n.s.    |
| Peripheral artery disease| 18.4% (26)   | 14.8% (8)   | 20.5% (17)  | n.s.    |
| Cerebral artery disease  | 25.4% (36)   | 29.6% (16)  | 22.6% (19)  | n.s.    |
| Chronic lung disease     | 25.4% (36)   | 25.9% (14)  | 26.2% (22)  | n.s.    |
| Atrial fibrillation      | 24.6% (35)   | 27.8% (15)  | 22.6% (19)  | n.s.    |
| Left ventricular ejection fraction (%) | 44.3 ± 12.6 | 48.0 ± 10.0 | 41.2 ± 13.8 | n.s. |
| Elective procedure       | 15.5% (22)   | 25.9% (14)  | 9.5% (8)    | .016    |
| ACS                      | 78.2% (111)  | 70.4% (38)  | 82.1% (69)  | n.s.    |
| STEMI                    | 28.8% (40)   | 14.8% (8)   | 36.9% (31)  | .006    |
| NSTEMI                   | 40.8% (58)   | 42.6% (23)  | 39.3% (33)  | n.s.    |
| Myocardial infarction    | 69.0% (98)   | 57.4% (31)  | 76.2% (64)  | .024    |
| Resuscitation prior or at presentation | 20.4% (29) | 7.4% (4) | 28.6% (24) | .002 |
| Cardiogenic shock        | 36.2% (51)   | 14.8% (8)   | 48.2% (40)  | .001    |
| Mechanical support       | 26.2% (37)   | 11.1% (6)   | 36.1% (30)  | .001    |
| Incomplete revascularization | 59.4% (82) | 33.3% (18) | 75.6% (62) | .001 |

Note: Characteristics of patients after percutaneous intervention of an unprotected left main coronary artery stenosis included in this registry. Values are given in mean ± SD or number of patients (percent of group). Significance was calculated comparing the low SYNTAX-1-group (score ≤ 32) and the high SYNTAX-1-group (score > 32).

Abbreviations: ACS, acute coronary syndrome; NSTEMI, non-ST-segment elevation myocardial infarction; n.s., nonsignificant (p-value > .05); STEMI, ST-segment elevation myocardial infarction.
In this retrospective study, we analyzed an all-comers collective of patients with ULMCA-PCI found nonsuitable for CABG by a heart team. We report clinical conditions and outcomes of these patients in respect of high and low SYNTAX-1-score. Our single center registry therefore reports real world data on an all-comers collective with ULMCA-PCI.

2 METHODS

We report data from a retrospective registry of all patients undergoing percutaneous coronary intervention of an ULMCA stenosis. Data was collected at a German university hospital of an all-comers collective.

2.1 Patient management

At our center, standard operating procedures encourage a heart team approach (including a cardiovascular surgeon and an interventional cardiologist) for all patients with significant ULMCA stenosis. In elective patients, the therapeutic options are then discussed with the patient and the procedure (CABG or PCI) is scheduled for the next workdays. If the ULMCA stenosis needs immediate treatment (e.g., when presenting in context of STEMI or cardiogenic shock), the heart team is formed by the cardiovascular surgeon and an interventional cardiologist in charge. A standard operating procedure for emergency CABG as well as ULMCA-PCI exists and both procedures can be performed on a 24/7 bases. All therapy decisions were based on current guidelines with respect of immediate and further treatments, secondary prevention and rehabilitation. The authors confirm that written consent for submission and publication has been obtained from the patients.

2.2 Data collection

All data presented derive from a single center retrospective registry analysis, were blinded to patient identity, and covered by an ethics approval (Ethics Committee of Albert-Ludwigs University of Freiburg, file numbers 223/17). To detect patients, all electronic medical records were screened by a computerized full text search using the search terms, “implantation of a stent” and “lesion of the left main coronary artery >50%.” All records of patients treated between January 1, 2014 and December 31, 2016 were screened. A total of 891 angiographic procedures were detected by the computerized full text search. ULMCA disease was defined as left main coronary artery disease (with stenosis in angiography >50%) not protected by a coronary bypass. A detailed manual medical chart review was performed and all patients with a culprit coronary lesion treated with PCI not including the ULMCA (or with bypass protected PCI of the left main) were excluded. Specifically, 735 hits were excluded since culprit lesion did not include the ULMCA; four hits were excluded since ULMCA-PCI was protected, nine hits were excluded since procedure was classified as Major adverse cardiovascular event (MACE) and one hit was excluded since stent did not include the left main.

| TABLE 2 | Scores and follow up |
|-----------------|---------------------|
| **Scores**      | All patients | SYNTAX ≤ 32 | SYNTAX > 32 | p-value |
| CHA2DS2-VASc score | 4.4 ± 1.6  | 4.4 ± 1.6  | 4.4 ± 16  | n.s.    |
| HAS-BLED score   | 3.2 ± 1.3  | 3.2 ± 1.3  | 3.1 ± 1.3  | n.s.    |
| SYNTAX1 LM score | 15.5 ± 4.0  | 13.9 ± 1.6  | 16.5 ± 4.7  | <.001 |
| SYNTAX1 score    | 37.4 ± 12.8  | 25.2 ± 5.5  | 45.3 ± 9.5  | <.001 |
| SYNTAX2 PCI score | 47.2 ± 14.0  | 42.0 ± 11.5  | 51.3 ± 14.5  | <.001 |
| SYNTAX2 PCI mortality (%) | 32.7 ± 26.5  | 23.1 ± 18.6  | 40.3 ± 29.4  | <.001 |
| SYNTAX2 CABG score | 45.5 ± 11.9  | 45.7 ± 12.2  | 45.3 ± 11.7  | n.s.    |
| SYNTAX2 CABG mortality (%) | 29.0 ± 21.1  | 29.5 ± 22.1  | 28.6 ± 20.4  | n.s.    |
| EUROScore II mortality (%) | 17.9 ± 16.2  | 10.6 ± 10.4  | 22.3 ± 17.5  | <.001 |

| Follow up        | All patients | SYNTAX ≤ 32 | SYNTAX > 32 | p-value |
|------------------|--------------|-------------|-------------|---------|
| MACE             | 68.3% (97)    | 61.1% (33)  | 71.3% (60)  | n.s.    |
| Presumed cardiac death | 33.3% (47)    | 22.2% (12)  | 36.9% (31)  | n.s.    |
| Repeated revascularization | 21.1% (30)    | 20.4% (11)  | 21.4% (18)  | n.s.    |
| Survival         | 54.2% (77)    | 64.8% (35)  | 50.0% (42)  | n.s.    |
| Follow-up telephone survey (days) | 763.7 ± 330.1 | 762.8 ± 315.5 | 795.5 ± 343.7 | n.s.    |
| NYHA class at telephone survey | 1.8 ± 0.9    | 2.0 ± 1.0 | 1.5 ± 0.7 | n.s.    |
| CCS class at telephone survey | 0.9 ± 0.9    | 1.0 ± 0.9 | 0.8 ± 1.0 | n.s.    |

Note: Scores and outcome of patients after percutaneous intervention of unprotected left main coronary artery stenosis. Values are given in mean ± SD or number of patients (percent of group). Significance was calculated comparing the low SYNTAX-1-group (score ≤ 32) and the high SYNTAX-1-group (score > 32). Abbreviations: MACE, major adverse cardiovascular event; n.s., nonsignificant (p-value > .05).
MACE were defined as hospitalization, myocardial infarction (MI), stroke, target lesion failure (TLF), or death. TLF was defined as indication for PCI including the ULMCA in coronary angiography performed at our center, or when reported in the telephone follow up (in case patients could not specify the location of stent implantation, a target lesion was presumed). For patients with more than one intervention at the ULMCA, the first PCI was included with the second one considered as major adverse cardiac event. Data given in this research was derived from the electronic patient files and records of the coronary angiographies performed at our center. SYNTAX-1- and 2-score were reassessed retrospectively for all patients by C.S. to minimize interobserver variability. The presence of an acute coronary syndrome (ACS) was defined by classification as MI or unstable angina (UA) by the treating physician as stated in the patient records. Elective procedures were defined as procedures in patients without acute coronary syndromes performed during office hours. For the telephone follow up, all patients were contacted by mail followed by a direct telephone call. Reasons for losing patients to follow up were mostly incorrect contact details or patient wish (rejecting the interview).

2.3 | Data analysis

For data analysis, SPSS (version 23, IBM Statistics) and Prism (version 5, GraphPad) were employed. For statistical analysis, unpaired \( t \)-test (for...
normally distributed variables) or Mann–Whitney test (for not normally distributed variables), Fisher’s exact test for binary variables, Log-rank test and Wald test were used as applicable and a p-value of ≤ 0.05 was considered statistically significant. Significance between the ROC curves was calculated using STATA and the roccomp command. Data are given as (mean ± SD) or (odds ratio [OR]; 95% confidence interval [CI]) if not stated otherwise.

3 | RESULTS

3.1 | Patient cohort

After manual review of all 891 patient records, a total of 142 patients (age 72.9 years, 23.2% females) with ULMCA-PCI between January 1, 2014 and December 31, 2016 could be included in the analysis. All patients either presented with a culprit lesion of the left main coronary artery or the culprit lesion included the left main in case of ostial culprit lesion of the left anterior descending or circumflex artery. A total of 78.9% of all patients presented with an acute coronary syndrome (compromised of UA 9.9%, STEMI 28.2%, and NSTEMI 40.8%), and only 15.5% of all procedures were performed electively. A total of 20.4% of all patients had to be mechanically resuscitated prior or during the percutaneous coronary intervention, and 26.2% of patients were on mechanical support (intra-aortic balloon pump, extracorporeal membrane oxygenation or an Impella® pump). A cardiogenic shock developed prior or during the PCI in 36.2% of all patients. Patient characteristics and cardiovascular risk factors are given in Table 1.

3.2 | SYNTAX-1-score

Average SYNTAX-1-score in the whole cohort was 37.4 ± 12.8. A total of 84 patients had a high SYNTAX-1-score at presentation defined as SYNTAX-1-score > 32. When comparing patients with high to low SYNTAX-1-score, we found that groups were similar with regard to preexisting comorbidities (see Table 1), including age, gender, and cardiovascular risk factors. The high SYNTAX-1-score group, however, compromised significantly more unstable patients with regard to acute MI, cardiogenic shock, and need for mechanical support. In the high SYNTAX-1-score group, only 9.5% of all ULMCA-PCIs were performed electively.

3.3 | Outcome

After a median follow up of 2 years, survival was 54.2% in the whole cohort, with higher survival in the low SYNTAX-1-score group (64.8%) not reaching statistical significance over the high SYNTAX-1 group (50.0%), see Table 2. The Kaplan–Meier survival curves are given in Figure 1. Major adverse cardiovascular events (MACE) were detected during follow-up in 68.3% of all patients, favoring the low SYNTAX-1-group (61.1% vs. 71.3%), but not reaching statistical significance. When focusing on the subgroups with cardiogenic shock or MI, we found similar survival curves in the low and high SYNTAX-1-score groups, discriminated by the acute presentation (Figure 1).

3.4 | Predictors of survival

Survival after ULMCA-PCI was strongly dependent on the clinical condition at presentation, see Table 3. Especially cardiogenic shock was a major predictor of unfavorable outcome in the low SYNTAX-1-score group with an odds ratio (OR) of 0.050 (95% confidence interval 0.01–0.45), as well as the high SYNTAX-1-score group (OR 0.056, 95% CI 0.02–0.17) as displayed by Figure 2. The same trend was observed for presentation with acute MI, also not reaching statistical significance in the low SYNTAX-1-score group. Other predictors like chronic kidney disease, atrial fibrillation, or chronic obstructive pulmonary disease did not reach statistical significance. SYNTAX-1-score, SYNTAX-2-PCI-score, and the EuroScore II were significant predictors of survival in the high SYNTAX-1-group, while only the EuroScore II reached statistical significance in the low SYNTAX-1-group (Figure 2).

When evaluating the area under the receiver operating characteristic (ROC) curve, EuroScore II predicted survival best with an AUC (c-index) of 0.83 compared to SYNTAX-2-PCI-score and SYNTAX-1-score (c-index 0.68 and 0.63, respectively) in the whole cohort. The

Univariate logistic regression of 2 year survival

| Predictor          | SYNTAX1 | Adjusted odds ratio (95% CI) for survival | p-value |
|--------------------|---------|------------------------------------------|--------|
| Planned procedure  | low     | 2.444 (0.59-10.2) | 0.219  |
|                    | high    | 1.757 (0.39-7.88) | 0.462  |
| Chronic kidney     | low     | 0.476 (0.15-1.56) | 0.219  |
|                   | high    | 0.556 (0.23-1.33) | 0.398  |
| Acute myocardial   | low     | 0.337 (0.10-1.14) | 0.380  |
|              | high    | 0.030 (0.01-0.24) | 0.001  |
| Cardiogenic shock  | low     | 0.050 (0.01-0.45) | 0.008  |
|                   | high    | 0.056 (0.02-2.17) | 0.011  |
| SYNTAX1 score      | low     | 0.994 (0.90-1.10) | 0.910  |
|                   | high    | 0.932 (0.88-0.98) | 0.013  |
| SYNTAX2 PCI score  | low     | 0.949 (0.90-1.01) | 0.074  |
|                   | high    | 0.953 (0.92-0.99) | 0.017  |
| EuroScore II       | low     | 0.887 (0.82-9.96) | 0.002  |
|                   | high    | 0.903 (0.87-0.94) | 0.001  |
discriminative ability of the SYNTAX-1-score was limited in both high and low SYNTAX-1-score group (c-index 0.65 vs. 0.63), while SYNTAX-2-PCI-score performed better (c-index 0.67 vs. 0.67). EuroScore II had the best discriminative ability (c-index 0.87 vs. 0.78). The ROC curves are illustrated in Figure 3.

4 | DISCUSSION

In this registry of ULMCA stenosis treated with PCI, we found that survival was 54.2% after a median follow up of 2 years, and that survival was significantly reduced in patients with cardiogenic shock or MI. The majority of patients undergoing ULMCA-PCI presented in acute conditions with high SYNTAX-1-score, and is therefore underrepresented in clinical trials. Prognosis was best predicted by the acute condition and the EuroScore II.

Outcome of patients in the SYNTAX-1-trial was driven by MACE rather than survival. In our research, survival was used as primary endpoint for most data analysis, since MACE and especially TLF are frequently underreported in registries. The survival rates in our study were comparable to patients with cardiogenic shock in the IABP-SHOCK II trial (1 year survival 49%), and significantly lower than reported by the SYNTAX-1-trial (30.0% all cause death in the PCI group at 5 years). Importantly, we report an all-comers patient collective considered not suitable for CABG by a heart team, including 78.2% of patients with ACS. Data from the SYNTAX-1-trial, however, was based on a stable patient collective.7 In patients with acute coronary syndromes and stenotic ULMCA, survival in registries is 50% over a 6-year follow-up. Previous studies report that in patients with ULMCA stenosis, presentation with STEMI is associated with poor prognosis compared to presentation with NSTEMI or UA, irrespective of the revascularization strategy. Therefore, survival rates after ULMCA-PCI reported by this registry featuring mostly ACS patients are in line with literature.

The average SYNTAX-1-score in our cohort was 37.4 ± 12.8, which is substantially higher than investigated in the SYNTAX-1-trial (score 29.1 ± 11.4). Patients screened for the SYNTAX-1-trial who could not be randomized were included in the SYNTAX-1-registry. These patients had a mean SYNTAX-1-score of 37.8, which is comparable to the SYNTAX-1-score reported by our registry. There is abundant evidence in literature that complex coronary anatomy, as evaluated by the SYNTAX-1-score, impacts outcome after PCI in stable patients. In unstable patients however, as suggested by this registry, the anatomical SYNTAX-1-score does not predict outcome reliably as demonstrated by the c-index below 0.65. The mediocre c-index of the SYNTAX-1-score is in accordance with data from other registries with reported AUCs of around 0.6. This might be explained by the fact that the SYNTAX-1-score was developed in stable coronary artery disease. Stratifying patients with ULMCA stenosis by SYNTAX-1-score might be insufficient since the anatomical SYNTAX-1-score neglects the clinical presentation.
When performing a ROC analysis on prediction of long term survival, we found that the EuroScore II is by far superior to the SYNTAX-1-score and SYNTAX-2-PCI-score ($p < .001$ and $p = .0023$, respectively). According to our data, the EuroScore II might be the best discriminator of prognosis. When comparing patients with high SYNTAX-1-score (>32) to patients with lower SYNTAX-1-score, literature suggests that patients with high score perform worse with PCI compared to CABG. In subgroup analysis, we found no evidence, that predictors of survival reported in this registry (specifically MI, shock or EuroScore II), perform differently in patients with high or low SYNTAX-1-score. Subgroup analysis in general however should be considered hypothesis generating, only.

Since only patients after ULMCA-PCI were included in this registry, we cannot comment on the best revascularization strategy of these patients or on a potential better outcome with CABG. Prospective data are needed to evaluate which revascularization strategy should be used in unstable patients and which score can guide the revascularization strategy.

5 CONCLUSION

In this registry, the majority of patients undergoing ULMCA-PCI presented in an acute condition and had a SYNTAX-1-score above 32. This cohort is underrepresented in clinical trials. Prognosis of both high and low SYNTAX-1-score groups was best predicted by the EuroScore II, and was significantly reduced in patients presenting with MI or cardiogenic shock. These data suggest that clinical decision making should mainly orientate on the clinical condition over the anatomical SYNTAX-1-score.

CONFLICT OF INTEREST

None.

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