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# Development and prospective validation of a risk stratification system for patients with syncope in the emergency department: the OESIL risk score

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## KEYWORDS

Syncope;  
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**Aims** Aim of the present study was the development and the subsequent validation of a simple risk classification system for patients presenting with syncope to the emergency departments.

**Methods and results** A group of 270 consecutive patients (145 females, mean age 59.5 years) presenting with syncope to the emergency departments of six community hospitals of the Lazio region of Italy was used as a derivation cohort for the development of the risk classification system. Data from the baseline clinical history, physical examination and electrocardiogram were used to identify independent predictors of total mortality within the first 12 months after the initial evaluation. Multivariate analysis allowed the recognition of the following predictors of mortality: (1) age >65 years; (2) cardiovascular disease in clinical history; (3) syncope without prodromes; and (4) abnormal electrocardiogram. The OESIL (Osservatorio Epidemiologico sulla Sincope nel Lazio) score was calculated by the simple arithmetic sum of the number of predictors present in every single patient. Mortality increased significantly as the score increased in the derivation cohort (0% for a score of 0, 0.8% for 1 point; 19.6% for 2 points; 34.7% for 3 points; 57.1% for 4 points;  $p < 0.0001$  for trend). A similar pattern of increasing mortality with increasing score was prospectively confirmed in a second validation cohort of 328 consecutive patients (178 females; mean age, 57.5 years).

**Conclusions** Clinical and electrocardiographic data available at presentation to the emergency department can be used for the risk stratification of patients with syncope. The OESIL risk score may represent a simple prognostication tool that could be usefully employed for the triage and management of patients with syncope in emergency departments.

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## Introduction

Syncope is a frequent symptom and is currently defined as a sudden and temporary loss of

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consciousness associated with a concurrent loss of postural tone, from which recovery is spontaneous and prompt.<sup>1,2</sup> Such symptom complex may be derived from multiple possible etiologies, ranging from benign conditions to life-threatening diseases, and should be carefully distinguished from all other states of altered consciousness, including vertigo, seizure and coma.<sup>1,2</sup>

Syncope represents a common clinical problem accounting for about 3% of all emergency room visits and up to 6% of hospital admissions.<sup>3-6</sup> Overall, syncope appears to be a major challenge for the practicing physician, who may be particularly concerned about the risk of subsequent adverse clinical events, such as sudden cardiac death.<sup>1,2</sup> Consequently, the triage and management of patients with syncope in the emergency department (ED) is usually considered as difficult and unrewarding, while relevant percentages of low-risk patients with syncope are admitted just for a brief period of clinical observation and monitoring.<sup>5,7</sup>

Aim of the present study was the development and the subsequent validation of a simple risk classification system for patients presenting to the ED with syncope. Such a prognostication tool could be employed for an appropriate, cost-effective triage and management of syncope patients in the specific setting of the ED.

## Methods

### Participating centers

Six general community hospitals of the Lazio region of Italy were included in the investigation for the recruitment of the initial derivation cohort and the development of the risk classification system (S. Filippo Neri-Rome, S. Spirito-Rome, C.T.O.-Rome, Fatebenefratelli-Rome, Belcolle-Viterbo, S. Camillo-Rieti).

### Derivation cohort

All patients older than 12 years presenting for syncope to the ED of one of the six hospitals, participating in the study from the 15 November 1997 to the 15 January 1998, were considered eligible for enrollment. Syncope was defined as a sudden and transient loss of consciousness and of postural tone with spontaneous recovery.<sup>1,2</sup> Patients with an already known seizure disorder and presenting a typical recurrence, with prolonged post-ictal recovery phase, were excluded. Patients presenting with only presyncope, dizziness or vertigo, without a clear loss of consciousness, were also

excluded. The patients had to provide informed consent to be included in the study. At the end of the 2-month scheduled period of recruitment the study, population comprised 270 consecutive patients (125 males and 145 females), with a mean age of 59.5±24.3 years (range, 14–88 years).

### Initial evaluation in the ED

The initial evaluation of the syncope patients was performed in the ED by the physician on duty, according to the OESIL algorithm, as described in a previous study.<sup>8</sup> Such work-up included a detailed history, a complete physical examination, a 12-lead electrocardiogram with rhythm strip, a hemoglobin count and a blood glucose test (finger stick). The entire data deriving from the initial evaluation were recorded in a prospective registry. Patients were considered to have cardiovascular disease in their clinical history in the following cases:

1. Previous clinical or laboratory diagnosis of any form of structural heart disease, including ischemic heart disease, valvular dysfunction and primary myocardial disease,
2. Previous diagnosis or clinical evidence of congestive heart failure,
3. Previous diagnosis or clinical evidence of peripheral arterial disease,
4. Previous diagnosis of stroke or transient ischemic attack.

Electrocardiographic recordings were evaluated by the emergency physician and subsequently reviewed by a cardiologist, only in case of a specific request. The tracings were considered abnormal in the following cases:

1. Rhythm abnormalities (atrial fibrillation or flutter, supraventricular tachycardia, multifocal atrial tachycardia, frequent or repetitive premature supraventricular or ventricular complexes, sustained or non-sustained ventricular tachycardia, paced rhythms),
2. Atrioventricular or intraventricular conduction disorders (complete atrioventricular block, Mobitz I or Mobitz II atrioventricular block, bundle branch block or intraventricular conduction delay),
3. Left or right ventricular hypertrophy,
4. Left axis deviation,
5. Old myocardial infarction,
6. ST segment and T wave abnormalities consistent with or possibly related to myocardial ischemia.

Electrocardiographic recordings showing non-specific repolarization abnormalities were not considered as abnormal.

### Clinical end point

The primary end point was death from any cause within 12 months of the initial evaluation in the ED and inclusion in the study. Such end point was preferred to cardiovascular mortality, as the latter has several possible inherent limitations, including incorrect documentation and inaccurate assessment in an environment with low-autopsy rates.<sup>9</sup> Follow-up data after discharge were obtained from the family physicians or through telephone follow-up and outpatient visitation. No patient was lost to follow-up.

### Statistical analysis and development of the risk score

A multivariate model for prognostication of the risk of experiencing the primary end point (death from any cause within 12 months of the initial evaluation in the ED) was developed. The model incorporated baseline clinical and electrocardiographic features that could be readily identified at presentation in the ED. The rationale for such an approach was to focus on information that could be collected in a relatively short period of time in the ED, thereby establishing a model that could be used for efficient triage and management without waiting for additional tests or results of a period of observation.

Univariate predictors of all-cause mortality during the 12 months following the initial evaluation were identified using unpaired Student's *t* test for continuous variables and  $\chi^2$  analysis for categorical variables. The Cox proportional hazards regression method was used to determine the relation of baseline characteristics to death during the 12-month follow-up. All variables, determined from the baseline evaluation, with a probability value lower than 0.10 in the initial univariate analysis, were considered potential predictors of the study primary end point. Continuous variables were arranged in a dichotomous fashion before being entered in the multivariate model. All the variables were analyzed in a stepwise fashion to develop Cox models of the study end point (12-month all-cause mortality).

As described in previous studies,<sup>10,11</sup> after the multivariate analysis, the OESIL risk score was developed for the initial derivation cohort using those variables that had been found to be significant

independent predictors of 12-month all-cause mortality. The OESIL risk score was constructed and calculated by the simple arithmetic sum of the number of independent end point predictors present in every single patient. Finally, the derivation cohort was stratified according to the presence of the multivariate predictors of mortality. Differences in mortality rates for increasing OESIL score values were assessed using the  $\chi^2$  for trend.

The discriminative ability (ability of the score to classify patients and overall predictive performance) of the OESIL risk score was calculated by measuring the area under the receiver operating characteristic (ROC) curve.<sup>12</sup> In general, an area under the ROC curve >0.75 is considered as consistent with a good discriminant ability.<sup>12</sup>

The cumulative risk of experiencing the primary end point (death from any cause within 12 months) was estimated by means of the Kaplan–Meier method. Survival curves of the two study cohorts and subgroups were then formally compared using the log–rank test.

Data analysis was performed using the spss statistical software package (spss 10.0, Chicago, Ill). A *p* value <0.05 was considered statistically significant.

### Validation cohort

The OESIL risk score was subsequently validated in a cohort of 328 consecutive patients (178 females and 150 males), with a mean age of 57.5±26.1 years (range, 14–82 years). These patients presented for syncope to the ED of two hospitals in Rome (S. Filippo Neri and Policlinico A. Gemelli), from the 1 August 1999 to the 31 January 2000, and provided informed consent to take part in the investigation. As for the derivation cohort, all patients included in the validation cohort underwent an initial evaluation in the ED including a detailed history, a complete physical examination, a 12-lead electrocardiogram with rhythm strip, a hemoglobin count and a blood glucose test. Also for this cohort, mortality data (12-month all-cause mortality) after discharge were obtained from the family physicians or through telephone follow-up and outpatient visitation. No patient was lost to follow-up. At the end of the scheduled 12-month follow-up period, the validation cohort was stratified according to the OESIL risk score at presentation, and the mortality rates for increasing score were compared with the derivation cohort. Besides, the areas under the ROC curves were compared in both the derivation and validation datasets.

**Table 1** Characteristics of patients included in the derivation cohort divided according to the occurrence of the primary end point

	Event-free patients	Death during follow-up	<i>p</i>
Patients	239	31	
Age >65 years	96 (40.1%)	27 (87.0%)	0.0001
Males	107 (44.7%)	18 (58.0%)	0.16
Hypertension	74 (30.9%)	18 (58.0%)	0.002
Cardiovascular disease in clinical history	57 (23.8%)	22 (70.9%)	0.0001
Diabetes mellitus	24 (10.0%)	8 (25.8%)	0.01
Previous syncopal spells	81 (33.8%)	6 (19.3%)	0.10
Syncope without prodromes	69 (28.8%)	25 (80.6%)	0.0001
Syncope-related traumatic injuries	31 (12.9%)	10 (32.2%)	0.004
Abnormal electrocardiogram	63 (26.3%)	19 (61.2%)	0.0001

## Results

### Derivation of the score

The primary end point (death from any cause within 12 months following inclusion in the study) occurred in 31 (11.5%) of the 270 patients in the derivation cohort. The death was considered cardiovascular in 18 (58.0%) of the 31 cases, non-cardiovascular in 3 (9.6%) of the 31 cases and of unknown origin in the rest of the patients (32.4%). As shown in Table 1, univariate predictors of mortality were: age >65 years, hypertension, cardiovascular disease in clinical history, diabetes mellitus, syncope without prodromes, syncope-related traumatic injuries and abnormal electrocardiogram. In the multivariate Cox proportional hazards analysis, the following factors were found to be significant independent predictors of the primary end point: age >65 years (risk ratio, 1.42; 95% confidence interval, 1.24–1.62;  $p < 0.001$ ), cardiovascular disease in clinical history (risk ratio, 1.34; 95% confidence interval, 1.19–1.49;  $p < 0.001$ ), syncope without prodromes (risk ratio, 1.13; 95% confidence interval, 1.06–1.21;  $p < 0.001$ ) and abnormal electrocardiogram (risk ratio, 1.29; 95% confidence interval, 1.16–1.43;  $p < 0.001$ ). As the parameter estimates for each of the four independent predictors of the primary end point were of similar magnitude, the OESIL risk score was calculated for every single patient by assigning a value of 1 when an independent predictor was present. Subsequently, all patients in the derivation cohort were categorized by the number of risk factors, as shown in Fig. 1. Notably, in the derivation cohort, the proportion of deaths occurring by 12 months increased with ascending OESIL risk score, ranging from 0% among those patients with a score of 0 to 57.1% among those with a score of 4 ( $\chi^2 p$  for trend  $< 0.0001$ ; Fig. 1). The area under the ROC curve was 0.897 (confidence interval,

0.820–0.975), indicating a good discriminant ability of the score.

### Validation of the score

The validation cohort showed similar baseline characteristics when compared with the derivation cohort (Table 2). During the 12-month follow-up period, 28 (8.5%) of the 328 patients included in the validation cohort died. The death was considered cardiovascular in 19 (67.8%) of the 28 cases, non-cardiovascular in 1 (3.5%) of the 28 cases and of unknown origin in the rest of the patients (28.7%). As for the derivation cohort, the OESIL risk score was calculated for every single patient included in the validation cohort by assigning a value of 1 when an independent predictor of mortality was present (age >65 years, cardiovascular disease in clinical history, syncope without prodromes, abnormal electrocardiogram). Subsequently, all the patients in the validation cohort were categorized by the number of risk factors. A significant pattern of increasing mortality as the OESIL risk score increased could also be noted in the validation cohort ( $\chi^2 p$  for trend  $< 0.0001$ ; Fig. 2), with event rates ranging from 0% among patients with a score of 0 to 52.9% for patients with a score of 4. Besides, the slope of the increase in mortality rates with increasing OESIL risk score was not statistically different in the two cohorts.

The area under the ROC curve in the validation cohort was 0.894 (confidence interval, 0.812–0.975), which was not significantly different from what had been previously found in the derivation cohort. This finding confirmed the predictive ability of the OESIL score in the validation cohort.

The Kaplan–Meier survival curves of the two study cohorts are shown in Fig. 3. The Kaplan–Meier actuarial estimates of all-cause mortality after 30, 180 and 360 days were 1.9, 7.1 and 11.5% in the derivation cohort and 1.6, 4.9 and 8.5% in the

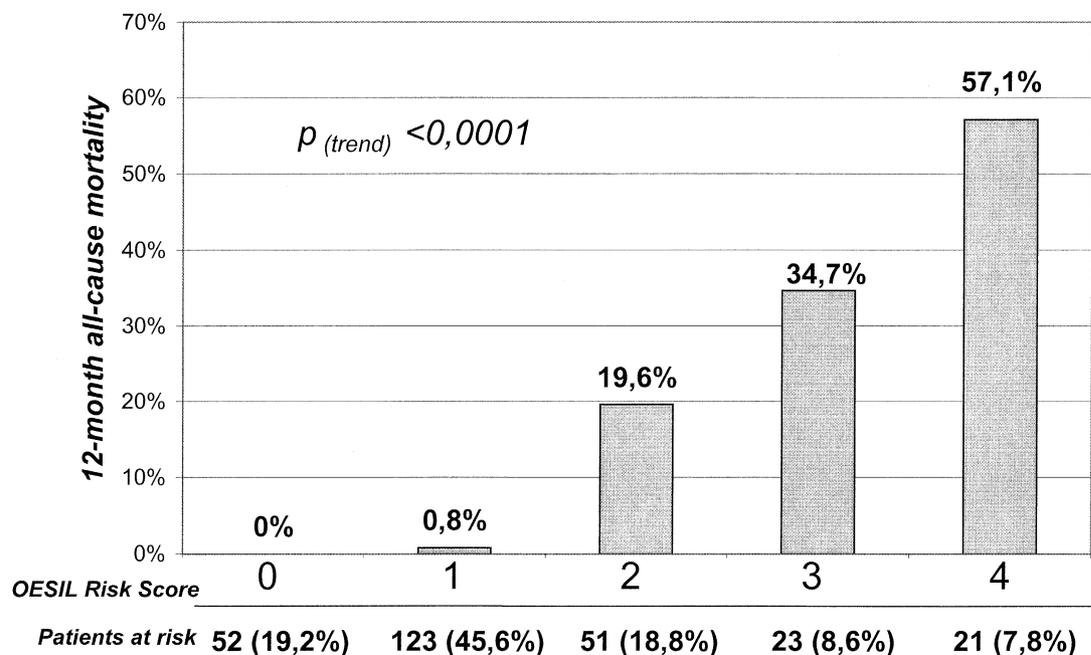


Fig. 1 Rates of 12-month all-cause mortality according to the OESIL score in the derivation cohort.

Table 2 Demographic and clinical characteristics of the derivation and validation cohorts

	Derivation cohort	Validation cohort
Patients	270	328
Age (years)	59.5±24.3	57.5±26.1
Males	125 (46.3%)	150 (45.7%)
Hypertension	92 (34.0%)	122 (37.2%)
Cardiovascular disease in clinical history	79 (29.2%)	108 (32.9%)
Diabetes mellitus	32 (11.8%)	42 (12.8%)
Previous syncopal spells	87 (32.2%)	104 (31.7%)
Syncope without prodromes	94 (34.8%)	124 (37.8%)
Syncope-related traumatic injuries	41 (15.1%)	58 (17.8%)
Abnormal electrocardiogram	82 (30.3%)	110 (33.5%)

validation cohort (log-rank  $p=0.223$ ). Besides, in both cohorts, no deaths were noted among patients with a score of 0–1 point for more than 6 months after the initial evaluation in the ED. The Kaplan–Meier survival curves of the patients included in the derivation cohort according to their score at presentation to the ED are shown in Fig. 4. Similar findings were noted in the validation dataset.

## Discussion

The results of this clinical investigation indicate that baseline clinical characteristics routinely obtained during the initial medical assessment of patients with syncope in the ED can be employed to construct a risk classification system that can effectively predict the subsequent risk for an

adverse outcome. In particular, the prognostic information deriving from a multivariate analysis in a large cohort of patients presenting with syncope to the ED were used to develop a convenient composite measure: the OESIL risk score. This prognostication tool incorporates demographic, historical and laboratory features that are independent predictors of 12-month all-cause mortality, namely age >65 years, cardiovascular disease in clinical history, syncope without prodromes and abnormal electrocardiogram.

The approach used for the development and validation of the OESIL risk score is similar to that taken by the TIMI investigators, who proposed a scoring system for the prognostic evaluation of patients with non-ST-elevation acute coronary syndromes and ST-elevation acute myocardial

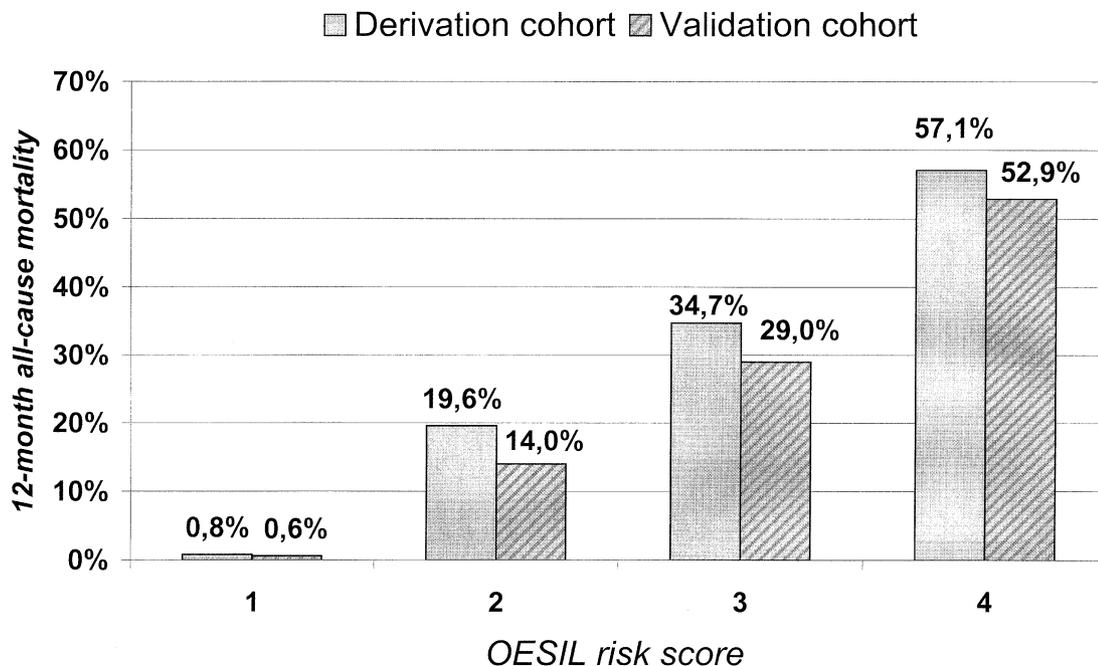


Fig. 2 Rates of 12-month all-cause mortality according to the OESIL score in the derivation and validation cohorts.

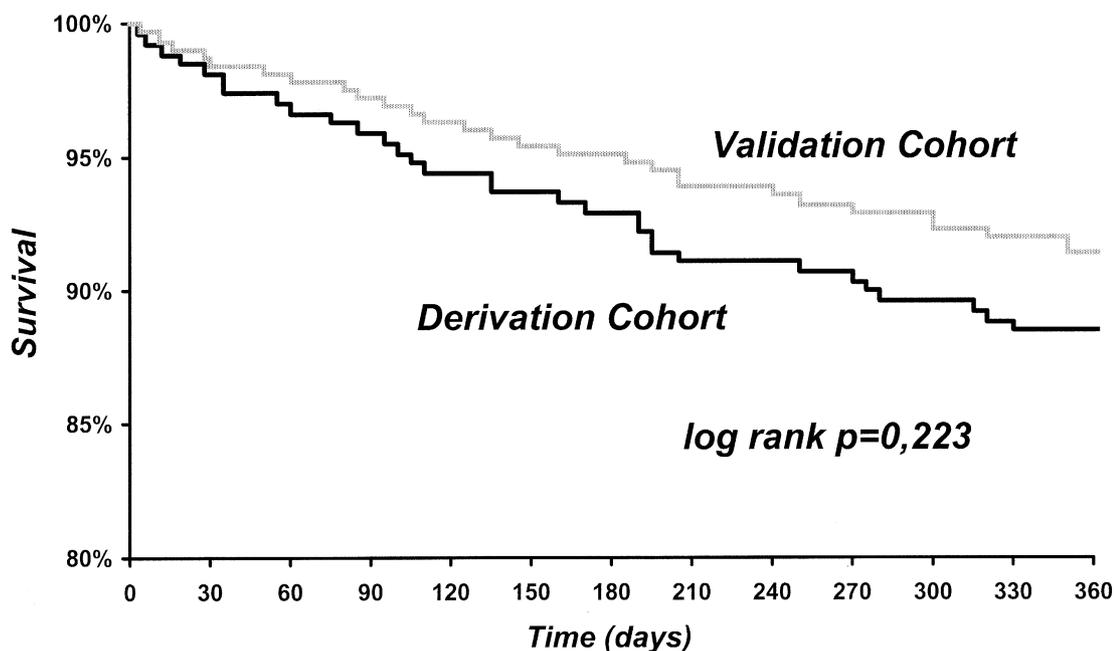


Fig. 3 Kaplan-Meier survival curves in the two study cohorts.

infarction.<sup>10,11</sup> In particular, the simple arithmetic sum of the number of independent predictors of mortality present in the single patient constitutes a score that can be easily calculated early at presentation to the ED without the aid of a computer. As a matter of fact, the OESIL risk score identified a significant gradient of mortality risk in the initial

derivation cohort of 270 consecutive patients with syncope from the ED of six general hospitals. Such a progressive significant increase in 12-month mortality as the OESIL score increased was prospectively confirmed in a second validation cohort of 328 patients with similar baseline characteristics. Notably, in both cohorts, the event rates raised

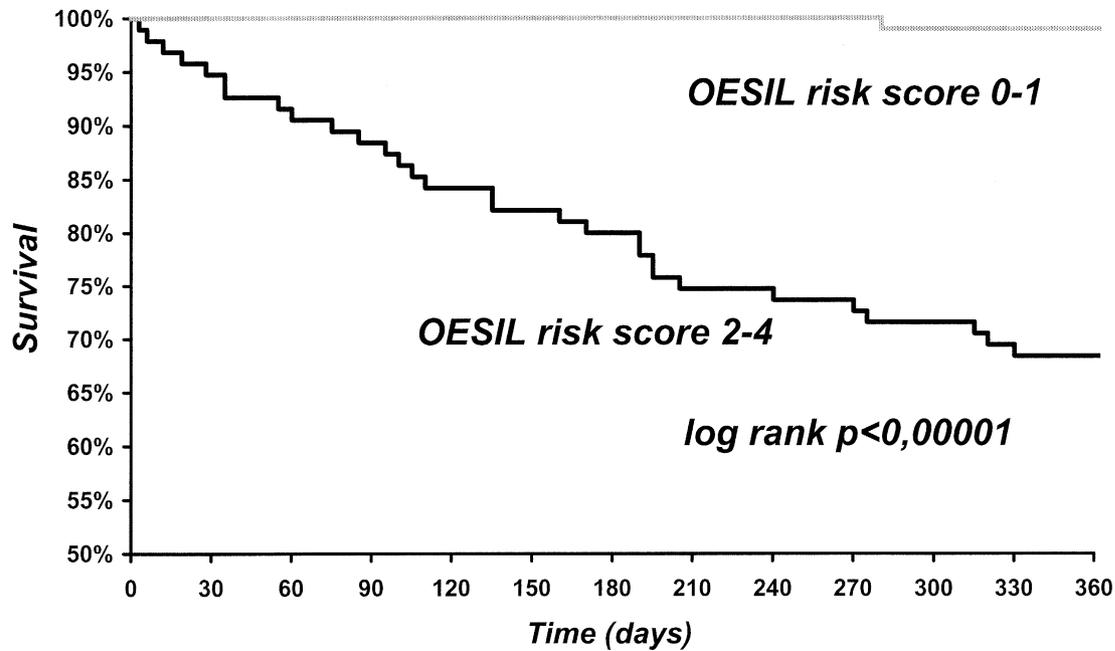


Fig. 4 Kaplan-Meier survival curves according to the score at presentation in patients included in the derivation cohort.

from 0% for patients with a score of 0 to more than 50% for patients with a score of 4.

The initial evaluation and management of patients with syncope is particularly demanding on the emergency physician, while cardiologists are often involved in the assessment of syncopal patients in the ED.<sup>2,13</sup> In fact, in most instances, patients are completely asymptomatic when they arrive in the ED and the differential diagnosis ranges from benign etiologies to serious life-threatening diseases. The responsibilities for the clinician include the identification of any underlying life-threatening process, the recognition of those patients who may require a further short-term diagnostic work-up, as well as the definition of the most appropriate setting where such an evaluation should occur.<sup>2,13</sup> Accordingly, the critical issue in the evaluation of patients with syncope in the ED is represented by the initial attempt to stratify the risk of the single patient for an adverse outcome, rather than diagnose the cause of every syncopal spell.<sup>13-15</sup>

Several previous studies have shown that historical data can help to risk-stratify patients with syncope in the ED. In particular, when considering a syncopal patient in the ED, the most predictive factors for subsequent adverse clinical events are represented by cardiovascular diseases in clinical history and advanced ages.<sup>4,16,17</sup> Besides, the absence of a prodromal phase is considered a possible marker of cardiac syncope, which in turn has been

associated with a negative prognosis.<sup>4,16,17</sup> As to the initial laboratory work-up, even if the diagnostic yield of electrocardiography in patients with syncope in the ED is considered as low as 5%, the presence of any significant abnormality in the electrocardiogram is known to impart an increased risk of adverse outcomes.<sup>17</sup> In accordance with such wealth of data, the prognostic relevance of all previously recognized historical and electrocardiographic features available at the time of presentation to the ED was confirmed in this clinical investigation. Moreover, in order to simplify and improve the initial approach to the syncopal patients in the ED, all prognostic elements were integrated in the composite measure of a score, which was appropriately validated. Such a simple prognostication tool could be particularly useful for the practicing physician in the ED as it may allow an early risk stratification of the single patient, thereby favoring an efficient initial triage. Furthermore, the OESIL risk score could be employed as a guide to the management of patients with syncope without the necessity of waiting for additional tests or results of a period of observation. In particular, low-risk patients (score, 0-1 point) could be considered for an out-patient evaluation and follow-up, while intermediate to high-risk patients (score, 2-4 points), showing a significant 1-year mortality, could be admitted for a more aggressive diagnostic and therapeutic approach. This clinical strategy may determine a significant reduction of

inappropriate admissions, which are known to be frequent. In fact, at least in European hospitals, more than 60% of patients presenting with syncope are admitted after the initial evaluation in the ED.<sup>5,6</sup>

A similar approach for the risk stratification of syncope patients in the ED has already been proposed by Martin et al., who reported that multivariate predictors of total mortality in their study population were an abnormal electrocardiogram, history of heart failure, age greater than 45 years and having no prior history of syncope.<sup>17</sup> However, Martin et al. performed their investigation in a single tertiary referral center in the USA and did not specifically focus on the generation of a simple scoring system to be employed in everyday clinical practice.

### Limitations of the study

Several limitations to our analyses should be acknowledged. The OESIL risk score described in this article was designed for early prognostication at the time of the initial presentation to the ED. Consequently, the relationship between the score and event rates described in this study may be altered in case this tool is applied in other clinical settings. Besides, the analysis did not consider the entire data collected after the initial presentation of the patients to the ED, including the effect of any therapeutic intervention and all the information derived from further laboratory assessment or hospitalization. Future refinements of the score may incorporate other variables with possible additional prognostic value; in particular, updating of the score and improvement of risk stratification with information concerning the specific cause of the syncopal spells is an area of further investigation.

The proposed prognostication tool incorporates specific historical findings, namely cardiovascular disease in clinical history. However, the clinicians must be aware that recording of only a careful and properly directed history is effective in ascertaining the actual occurrence of any previous cardiovascular event. Consequently, when uncertain previous symptoms, such as atypical chest pain, or non-clearly substantiated previous cardiovascular diagnosis are reported, the ED physician should not include such elements in the computation of the score.

### Conclusions

The OESIL scoring system may represent a useful means for an early risk stratification of patients

with syncope in the routine clinical practice of the ED. Moreover, the OESIL risk score may allow more accurate disposition and targeting of diagnostic procedures and therapeutic interventions.

## Appendix A

### OESIL study investigators

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