# VALIDATION OF SAPS-3 AND APACHE-III IN MEDITERRANEAN AREA

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***ABSTRACT***

***Introduction****: The objective of this study was to assess the SAPS-3 and APACHE-III prognosis systems in intensive care unit (ICU) patients in Mediterranean area.*

***Methods****: We studied patients admitted to the ICU in six hospitals in Spain from 2006 to 2012. Data were collected to assess SAPS-3 and APACHE-III in the prediction of death. Area under ROC curve was used to assess discrimination and Hosmer-Lemeshow test was used to assess agreement between observed and predicted mortality.*

***Results****: We have studied 2832 patients, aged 61.24±15.95 years. Hospital mortality was 16.55%. The probability of death was 17.03% by the SAPS-3 general equation and 17.63% by our geographical area equation. The Hosmer-Lemeshow test result for the general equation was 22.27 ($p<0.05$) and 34.86 ($p<0.05$) for the Spanish equation. The discrimination of SAPS-3 (ROC curve) was 0.846 (0.825-0.867).*

*Furthermore, with data collected from patients admitted to 4 of these hospitals, APACHE-III was calculated.*

*The sample was formed with 1686 patients, aged 61.95±15.89 years. ICU and hospital mortality were 11% and 14.89%, respectively. Mortality predicted by APACHE-III was 16.88%. The Hosmer-Lemeshow test was 22.64 ($p<0.05$). The discrepancies were statistically significant. The discrimination of APACHE-III for hospital mortality (ROC curve) was 0.884 (0.861–0.907).*

***Conclusions****: Our study shows a good discrimination of SAPS-3 and APACHE-III but APACHE-III was performed better than SAPS-3. There were discrepancies between predicted and observed mortality; SAPS-3 specific to our geographic area had the largest discrepancies. The differences between observed and expected mortality were small but statistically significant.*

***Key words****: Prognosis system, Severity of illness, Intensive care, mortality.*

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## Introduction

Intensive care unit (ICU) patients present high severity and mortality. Is, therefore, very important for every ICU, compare the severity and mortality of their patients, with that in other hospitals. This is the function of prognosis systems.

A large number of prognosis systems have been created specifically for intensive care (APACHE, SAPS, and MPM)[1-9], which have multiple versions. Constant improvement of these instruments is necessary, as well as adjustment to diagnosis and treatment changes that occur over time. Because of this, it is necessary to establish consecutive versions. This process will, probably, continue in the future.

The APACHE system[5-8] is the most popular and frequently used prognostic system in ICU. APACHE-II[6] is the most used system today, although there are new versions. The latest version is APACHE-IV[8]. The APACHE-III[7] had significant methodological innovations to evaluate ICU mortality and stay. In Spain, a validation study was conducted and it was observed that the calibration was not adequate[10]; after this, a model was customized to Spain was developed[11], and was analyzed later

in traumatic patients[12]. There was good calibration and discrimination, but validation in a multicenter study has not been performed.

The latest version of the MPM system is MPM-3[9], and the current version of the SAPS system is SAPS-3, which is widely used[4]. When a prognosis system is created, it is necessary to test its performance in both the same investigation group in which they were developed and different ones. Some studies have been carried out on SAPS-3 in different populations and situations: Austria[13], Italy[14], Brazil[15], and Korea[16]. We recently published a study that evaluated SAPS-3 in Spain[17].

The objective of the present study was to assess the SAPS-3 and APACHE-III prognosis systems in ICU patients of Mediterranean area.

## Materials and methods

This study was performed in several Spanish ICUs: Santa Ana Hospital in Motril (Granada), Carlos Haya Hospital in Málaga, Virgen de las Nieves Hospital in Granada, Fuenlabrada Hospital (Madrid), Infanta Margarita Hospital in Cabra (Córdoba), and Neuro-traumatologic Hospital in Jaén. We studied all patients admitted consecutively during a period, which was different depending on each hospital, and the minimum period of participation in the study was 2 months. That period was: from January to April 2006 in Virgen de las Nieves Hospital in Granada; from June 2006 to October 2007 in Santa Ana Hospital in Motril; throughout the whole of 2011 in Fuenlabrada Hospital; and two months in 2011 and two months in 2012 in Neurotraumatologic Hospital in Jaén, in Infanta Margarita in Cabra, and in Carlos Haya Hospital in Málaga. The study was approved by the ethics committees of each hospital.

The protocol we used to collect data and the analysis instruments used in this study had been carried out in Virgen de las Nieves for several years where some authors have worked, and through this activity, they have published some articles along the same lines[10, 11, 12]. An updated protocol was used by Santa Ana Hospital in 2006 and for the other hospitals during 2011.

In four of the hospitals included in our study (Santa Ana Hospital in Motril (Granada), Carlos Haya Hospital in Málaga, Infanta Margarita Hospital in Cabra (Córdoba), and Neuro-traumatologic Hospital in Jaén), we used a common protocol that collected administrative data, age, length of ICU and hospital stay, previous admission location and comorbidities, diagnosis, etc. Furthermore, as well as physiological medical laboratory variables in the first hour before and after ICU admission and during the first 24 hours, all the necessary variables for the SAPS-3 and APACHE-III prognosis system calculations were used. Variables were collected in one database to be used according to necessity. In Virgen de las Nieves Hospital (Granada), a different protocol was used, and this allowed only calculations for SAPS-3, and the collecting, in one database, all the variables that were necessary for SAPS-3 calculation. Finally, in Fuenlabrada Hospital, they used the SAPS-3 online calculator, without saving all the values of the variables in all cases for the index calculation.

We studied the ICU and hospital mortality of the episode. We also specified whether the patients were admitted for acute coronary syndrome. These patients group represented a large group that we expected to report in a separate article, but we have included in this study. The protocol was gathered by trained personnel from the participating hospitals.

Data were expressed as means ± standard deviation and qualitative variables were expressed as absolute and relative frequencies or percentages. The PSPP and R statistical programs were used. Hosmer-Lemeshow test was used to assess agreement between observed and predicted mortality[18]. In this analysis, $p>0.05$ shows a goodness of fit. Area under the ROC curve was used to assess discrimination[19]. The standardised mortality ratio (SMR) was calculated as the relationship between the numbers of observed and expected deaths.

## Results

The sample was composed of 2832 patients, aged 61.24±15.95 years. ICU mortality was 11% and hospital mortality was 16.55%. The types of patients are shown in Table 1.

SAPS-3 score was 45.58±14.07 points. The probability of death by the general equation was 17.03% and the result of Hosmer-Lemeshow test for the general equation was 22.27 ($p<0.05$) (Table 2a and Figure 1). SMR for the SAPS-3 general equation was 0.91 (0.83-0.99).

For the South-western Europe equation of the SAPS-3 prognosis system, probability of death was estimated to 17.63%, and Hosmer-Lemeshow test was 34.86 ($p<0.05$) (Table 2b and Figure 2). In both cases (South-western Europe equation and general

equation), we observed differences between observed and predicted mortality that were statistically significant.

Standardised mortality ratio (SMR) for the SAPS-3 South-western Europe equation was 0.88 (0.80–0.96). In both cases, (general equation and south-west Europe equation) the confidence interval of SMR did not include "1".

| Type of patients | N | % | SAPS-3 | Predicted mortality (a) | Hospital mortality |
|---|---|---|---|---|---|
| Medical | 1615 | 57% | 49.60±13.71 | 21.41% | 19.69% |
| Scheduled Surgery | 951 | 33.6% | 37.23±10.42 | 7.58% | 6.83% |
| Unscheduled surgery | 266 | 9.4% | 51.03±14.26 | 24.21% | 21.88% |
| Total | 2832 | 100 | 45.58±14.07 | 17.03% | 15.57% |

**Table 1**: Basic demographic data. Type of admission.
*(a) Predicted mortality by general equation*

| Probability of death (a) | nº Cases | nª death observed | nº death predicted | nº survivors observed | nº survivors predicted |
|---|---|---|---|---|---|
| <0.1 | 1485 | 55 | 68.53 | 1430 | 1416.67 |
| 0.1-0.2 | 511 | 54 | 73.70 | 457 | 437.30 |
| 0.2-0.3 | 330 | 60 | 80.43 | 270 | 249.57 |
| 0.3-0.4 | 164 | 59 | 57.66 | 105 | 106.34 |
| 0.4-0.5 | 97 | 54 | 43.83 | 43 | 53.17 |
| 0.5-0.6 | 101 | 58 | 54.25 | 43 | 46.75 |
| 0.6-0.7 | 64 | 42 | 41.07 | 22 | 22.93 |
| 0.7-0.8 | 54 | 37 | 40.42 | 17 | 13.58 |
| 0.8-0.9 | 23 | 19 | 19.55 | 4 | 3.45 |
| >0.9 | 3 | 3 | 2.79 | 0 | 0.21 |

**Table 2a**: Performance of the SAPS-3 Score . Goodness of fit of general SAPS-3. Model by Hosmer-Lemeshow.
*Hosmer-Lemeshow = 22.27*
*DF 8 , p <0.05*
*(a)Probability of death based in general equation*

The discrimination of SAPS-3 for hospital mortality assessed with the area under the ROC curve was 0.846 (0.825-0.867).

In Table 3 we show observed and predicted mortality in each hospitals included in this study. In 5 hospitals mortality observed was lower or similar than predicted, in one hospital observed mortality was higher than predicted for both equations.

There were 576 patients (20.3% of total) admitted with ST segment elevation myocardial infarction (STEMI) and not ST segment elevation myocardial infarction (NSTEMI). Hospital mortality of these patients was 8.16% and predicted mortality by the general equation was 12.33% and 13.05% by the South-western Europe SAPS-3 model. SMR by general equation was 0.66 (0.87-0.47) and by South-western SAPS-3 model was 0.63 (0.45-0.81).

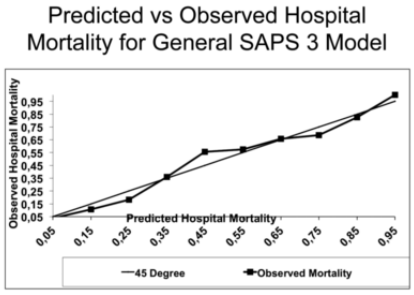


**Fig. 1**: Predicted versus Observed hospital mortality for General SAPS-3 model. Lines mean SAPS 3 predicted mortality per deciles. Squares mean SAPS 3 observed mortality per deciles.

| Probability of death (a) | nº Cases | nª death observed | nº death predicted | nº survivors observed | nº survivors predicted |
|---|---|---|---|---|---|
| <0.1 | 1372 | 47 | 62.49 | 1325 | 1309.51 |
| 0.1-0.2 | 559 | 47 | 79.15 | 512 | 479.85 |
| 0.2-0.3 | 355 | 61 | 85.94 | 295 | 269.06 |
| 0.3-0.4 | 174 | 59 | 59.59 | 1115 | 114.41 |
| 0.4-0.5 | 127 | 68 | 56.48 | 59 | 70.52 |
| 0.5-0.6 | 114 | 66 | 61.81 | 48 | 52.19 |
| 0.6-0.7 | 58 | 39 | 37.48 | 19 | 20.52 |
| 0.7-0.8 | 49 | 34 | 36.17 | 15 | 12.83 |
| 0.8-0.9 | 29 | 17 | 17.45 | 4 | 3.55 |
| >0.9 | 3 | 3 | 2.73 | 0 | 0.27 |

**Table 2b**: Performance of the SAPS-3 Score. Goodness of fit of South - western. SAPS-3 model by Hosmer-Lemeshow - $X^2$ statistic.
*Hosmer-Lemeshow = 34.86, DF=8, 0<0.05*
*(a) Probability of death based in South-Western equation*

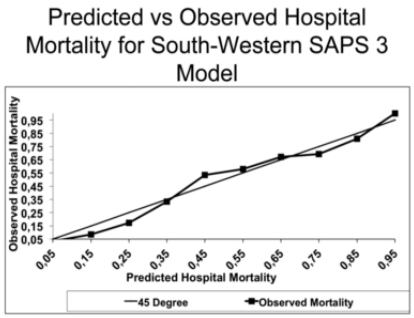


**Fig. 2**: Predicted versus Observed hospital mortality for South-Western SAPS-3 model. Lines mean SAPS 3 predicted mortality per deciles. Squares mean SAPS 3 observed mortality per deciles.

| Hospital | N | Observed Mortality | Predicted mortality by general equation | Predicted mortality by our geographical | SMR general equation | SMR geographical area equation |
|---|---|---|---|---|---|---|
| 1 | 568 | 0.209 | 0.226 | 0.232 | 0.93(0.76-1.09) | 0.9(0.74-1.26) |
| 2 | 461 | 0.18 | 0.18 | 0.184 | 1.01(0.79-1.23) | 0.98(0.77-1.19) |
| 3 | 1085 | 0.113 | 0.119 | 0.125 | 0.95 (0.78-1.11) | 0.90(0.74-1.06) |
| 4 | 155 | 0.136 | 0.23 | 0.24 | 0.58 (0.33-0.83) | 0,56(0,32-0.80) |
| 5 | 130 | 0.276 | 0.207 | 0.213 | 1.34(0.9-1.77) | 1.3(0.87-1.72) |
| 6 | 433 | 0.136 | 0.183 | 0.188 | 0.74(0.56-0.93) | 0.72(0.54-0.91) |
| Total | 2832 | 0.156 | 0.170 | 0.176 | 0.91(0.83-0.99) | 0.88(0.80-0.96) |

**Table 3**: Observed and predicted mortality at different hospitals by SAPS-3.

| Probability of death (a) | nº Cases | nª death observed | nº death predicted | nº survivors observed | nº survivors predicted |
|---|---|---|---|---|---|
| <0.1 | 912 | 26 | 42.50 | 886 | 869.50 |
| 0.1-0.2 | 334 | 31 | 47.52 | 303 | 286.48 |
| 0.2-0.3 | 164 | 29 | 40.31 | 135 | 123.69 |
| 0.3-0.4 | 72 | 25 | 25.10 | 47 | 46.90 |
| 0.4-0.5 | 59 | 30 | 26.29 | 29 | 32.71 |
| 0.5-0.6 | 36 | 19 | 19.62 | 17 | 16.38 |
| 0.6-0.7 | 35 | 27 | 22.86 | 8 | 12.14 |
| 0.7-0.8 | 33 | 26 | 24.72 | 7 | 8.28 |
| 0.8-0.9 | 29 | 26 | 24.24 | 3 | 4.76 |
| >0.9 | 12 | 12 | 11.23 | 0 | 0.77 |

**Table 4**: Performance of the APACHE III system. Goodness of fit of APACHE III (Spanish version) by Hosmer-Lemeshow $X^2$ statistic.
*Hosmer-Lemeshow =22.64, DF =8, p<0.05*
*(a) Probablity of death based in Apache III model (Spanish customization) equation*

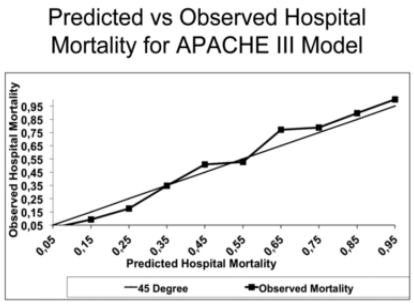


**Fig. 3**: Predicted versus Observed hospital mortality for Apache III system customized for Spanish ICU patients. Lines mean SAPS 3 predicted mortality per deciles. Squares mean SAPS 3 observed mortality per deciles.

This type of patient was included in the present study but they will be studied more carefully and individualized in a new study.
For patients admitted to four hospitals, we also collected the information needed to calculate APACHE-III. The sample was consisted of 1686 patients, aged 61.95±15.89 years. ICU mortality was 11% and hospital mortality was 14.89%; mortality predicted by APACHE-III was 16.88%. The Hosmer-Lemeshow test result for APACHE-III was 22.64 ($p<0.05$). The discrepancies were statistically significant (Table 4 and Figure 3). The SMR for the APACHE-III system was 0.88 (0.77-0.99). The discrimination of APACHE-III for hospital mortality assessed with the area under the ROC curve was 0.884 (0.861-0.907).

Of 1686 patients, 372 (22.1% of total) were admitted with STEMI and NSTEMI. Hospital mortality of these patients was 9.41% and predicted mortality by APACHE-III was 12.91%. The SMR of coronary patients was 0.73 (0.49-0.97).

In Table 5 we show observed and predicted mortality in each hospitals included in this study. In 3 hospitals mortality observed was lower than predicted, in one hospital observed mortality was higher than predicted.

| Hospital | N | Observed Mortality | Predicted mortality by APACHE III | SMR by APACHE III equation |
|---|---|---|---|---|
| 1 | 526 | 0.194 | 0.196 | 0.99 (0.80-1.18) |
| 2 | 888 | 0.106 | 0.15 | 0.71 (0.57-0.85) |
| 3 | 148 | 0.135 | 0.137 | 0.99 (0.56-1.42) |
| 4 | 124 | 0.282 | 0.22 | 1.28 (0.86-1.7) |
| Total | 1686 | 0.149 | 0.168 | 0.88 (0.77-0.99) |

**Table 5**: Observed and predicted mortality at different hospitals by APACHE III.

## Discussion

Our study shows that SAPS-3 and the Spanish version of APACHE-III have an inadequate calibration in Spain; both overestimate mortality. Although the differences between predicted and observed mortality were not excessive, they were statistically significant. We think that both prognostic systems can be used in Spain to quantify patients' severity and control mortality in Spanish ICUs.

When a prognosis index is created, it is necessary, as a first step, to carry out the first validation. Subsequently, it is necessary to perform an external validation. In the case of SAPS-3, several validation studies have been carried out. In an Austrian study in 2008, in a sample of 2060 patients, the original SAPS-3 score showed an overestimated hospital mortality. For this reason, the model was adapted for that country[13].

In the Italian external validation study in 2009, with a sample of 28,357 patients in 147 ICUs, the SAPS-3 score showed a bad calibration in a large sample of patients. General and southern-Europe-Mediterranean equations overestimated hospital mortality, with SMR values of 0.73 and 0.71, respectively[14]. In Brazil, a study carried out in 2010 in two units from two different third-level hospitals showed a correct discriminatory power with SMR 1.04, and observed mortality was quite close to the predicted one (10.8% vs 10.3%, respectively), although this was a relatively small study[15].

In the study carried out in Korea in 2011, SAPS-3-predicted mortality was 42% compared with 31% observed mortality[16], although this study was conducted in only one unit, with 633 patients. As we can see, differences between observed and predicted mortality are large, with real mortality being less than expected, just like our current study and the Italian and Austrian ones.

In Spain, a multicenter validation study, such as the present study, had not been carried out before. Previously, we published the validation of SAPS-3[17] and now we publish in this article the results with SAPS-3 and APACHE-III. Previously, another group has published one study in only one hospital (20), with 935 patients. It showed a SMR of 0.71 (0.56-0.90) for the general equation, and a SMR of 0.69 (0.55-0.87) for the specific geographical area equation. A study by Castellon group, which has been reported at a congress but has not been published yet[21], showed a SMR of 0.85.

Our study shows an appropriate discrimination of SAPS-3, using the area under the ROC curve, of 0.846 (0.825-0.867). It is important to note that to improve discriminatory power, it would be necessary to collect a larger number of variables, and consequently, the process would be more laborious. Additionally, it is worth remembering the advantage of data collection during the first hour of admission, as is done in the SAPS-3 system.

With respect to calibration, our study shows less mortality than expected, both for the general equation (Hosmer-Lemeshow Test (H) =22.27) and for the equation for our specific geographical area (Hosmer-Lemeshow Test (H) =34.86). The SMR was 0.91 for general equation and was 0.88 for the equation for our specific geographical area. We can see that the differences are not excessive but are statistically significant, with higher differences for the equation for our geographical area.

Although in the SAPS-3 model the agreement between observed and predicted mortality was not enough, we think that this does not invalidate the SAPS-3 model, because these differences between predicted and observed mortality are not excessive and discrimination is high and our values are similar to those observed in the original study.

These data are similar to those reported by other authors in our environment in a group of patients in only one unit[20], or presented at a congress but not yet published, such as the Castellón group's data[21], with a SMR of 0.85. At the Spanish Society of Intensive and Critical Care Medicine and Coronary Units (SEMICYUC) congress, the Fuenlabrada group also presented a communication about this issue in which the conclusions were similar to ours[22]. In conclusion, in our country, just as we have seen in other countries[13-16], the SAPS-3 score overestimates mortality.

The other prognosis system analyzed in our study is APACHE-III. The latest version of the APACHE system is APACHE-IV. In our country, there have been no multicenter studies to evaluate its performance. As mentioned previously, the APACHE-III version was evaluated in our country, which showed that mortality was underestimated[10]. A customization for our country was made[11] and a posterior evaluation showed the correct performance[12], but no multicenter study similar to this study was performed.

The study of customization for Spain of APACHE III was published in 1998. Although time has passed, in the current study APACHE-III have showed an acceptable performance and overestimated mortality, same as SAPS-III. Although the differences between predicted and observed mortality were significant, as with SAPS-III, they were not important (SMR for APACHE-III prognostic system was 0.88 (0.77-0.99) and for SAPS-3 general equation was 0.91 (0.83-0.99) and for southwest equation was 0.88 (0.80-0.96)).

This study shows that with the SAPS-3 and APACHE-III systems, there are significant differences between predicted and observed mortality, espe-

cially in patients with coronary heart disease (STEMI and NSTEMI) with low SMR values. The SMR values for SAPS-3 and APACHE-III were 0.66 (0.47-0.87) and 0.73 (0.49-0.97), respectively. With both of them, the confidence interval did not include "1" and the mean SMR was very low, reflecting a significant discrepancy between observed and predicted mortality.

As mentioned previously, we intend to study these patients individually in a specific study. If bad calibration data are confirmed, it will be necessary to make a special calibration for these patients. Previously, the original version of APACHE-III showed a bad calibration in acute myocardial infarction (AMI) patients[23]. Subsequently, a calibration of these patients was performed.

There are articles that show a bad calibration of the SAPS-3 system in coronary patients[24]. Previously, we have published a study showing that the Killip classification complemented APACHE[25] and this may be useful for improving other prognostic systems such as SAPS-3. Our study shows that, for coronary patients, there are problems of calibration with APACHE-III and greater problems with SAPS-3, with a mean SMR that is very far from "1", similar results have been published with SAPS-3 in coronary patients[24].

One of the big differences between the SAPS and APACHE systems is that the APACHE system includes a diagnostic classification, and this classification has increased the categories with each new version of the APACHE system. The SAPS system had avoided the use of a diagnostic classification although SAPS-3 includes some diagnoses, but STEMI and NSTEMI are not included. We think that including a diagnostic classification can improve the SAPS system. Some of our previous studies have shown the importance of diagnostic classification in prognosis systems[26-27] and we think that this issue requires further study.

There are several limitations to our study. One of these is the sample size, because the number of patients included in the study is not as big as other studies that include more than 20,000 patients[14]. However, our study includes enough patients to reach statistically significant conclusions, and has a similar number of patients to that used in other studies of this kind[13].

Another limitation is not including a greater number of hospitals, to make the study more representative. Nevertheless, our study includes enough hospital to obtain a general conclusion, with different sized hospitals, kinds of patients (surgical, cardiac, transplant, etc), and geographical areas. Furthermore, the fact that the results are quite similar in all the hospitals and are similar to those in a congress report from other hospitals not included in this study, supports the validity of our results, allowing us to generalize them to the rest of the country.

Another limitation could be that the protocol we used was different in two hospitals and data collection had been carried out at different times. We think that this factor does not affect the quality of the study because the investigation was carefully carried out and the requirements were checked; for example, all consecutively patients admitted to ICU, and intermittent checking of previously collected data. The database allowed us to check strange values, to check the online SAPS-3 calculator, etc. Besides, the fact that our results in the different participating hospitals were similar allows us to trust in the quality of our study.

## Conclusion

SAPS-3 and APACHE-III have good discrimination, with APACHE-III having better discrimination than SAPS-3. There were discrepancies between predicted and observed mortality with the two instruments. The largest discrepancies were with the version of SAPS-3 specific to our geographical area. The differences between observed and expected mortality were small but statistically significant. We think that these differences do not invalidate these prognosis systems even though the differences were statistically significant. These systems can be used to quantify patient severity and for quality control of ICU patient mortality in Mediterranean area. However, we think they should be improved in the future for the evaluation of coronary heart disease patients (STEMI and NSTEMI), in whom we detected a bad calibration.

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***Abbreviations:***
*AMI: acute myocardial infarction*
*APACHE: Acute physiology and chronic health evaluation*
*ICU: intensive care unit*
*MPM: Mortality Probability Models*
*NSTEMI: not ST segment elevation myocardial infarction*
*OR: odds ratio*
*SAPS: Simplified Acute Physiologic Score*
*SEMICYUC: Spanish Society of Intensive and Critical Care Medicine and Coronary Units*
*SMR: standardised mortality ratio*
*SS: statically significant*
*STEMI: ST segment elevation myocardial infarction*

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