

**The “*Italian CABG Outcome Study*” - Short-term outcomes in patients with
Coronary Artery Bypass Graft Surgery.**

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ABSTRACT

Objectives- During the last decade, a worldwide growing interest in evaluating performance of health services through “outcome studies” took place. This study started in early 2002 and represents the first National Health System (NHS) experience to evaluate adjusted performance indicators at national level. The aim of this study was to compare 30 days mortality after coronary artery bypass graft (CABG) between cardiac surgery centres, adjusting by confounding risk factors.

Methods- All patients, aged 15-99 years, undergoing a CABG intervention after 1st January 2002 in 82 participating Centres were eligible for this observational longitudinal study. For each patient, data on severity and risk factors were collected (type of procedure, haemodynamic condition, comorbidities, recent myocardial infarction and unstable angina, ventricular function, emergency condition, vital status at 30 days).

Using a multiple logistic regression analysis the best predictive model was developed for risk adjustment; a cross validation procedure was applied; specific risk adjusted mortality rates (RAMR) were estimated. The overall study population was used as reference standard.

Results- 34,310 isolated CABG were performed in 64 of the 82 participating centres. Thirty days mortality resulted 2.61%, ranging from 0.33% to 7.63%; eight centres presented a RAMR significantly lower and seven significantly higher than the reference.

Conclusions-The study provides valid measures of the heterogeneity between outcomes of the Italian cardiac surgery centres, to support decision making by NHS management and individual patients. Although not statistically significant, RAMR dropped from year 2002 to 2004 (2.8% to 2.4%) suggesting that this comparative outcome assessment can contribute to the improvement of performances in cardiac surgery.

Key words: coronary artery bypass graft, outcome, risk-adjustment, mortality

INTRODUCTION

Worldwide interest has increased over the last 10 years in evaluating hospital performance through the assessment of actual results of patients care^[1-4]. Outcome based quality assessment in health care has been a growing interest for policymakers, administrators and clinicians. The most significant examples of outcomes studies are mainly related to cardiac surgery, particularly to coronary artery by-pass graft (CABG) and come from the United States, Canada and the United Kingdom^[5-11]. These studies allowed the public to have systematic access to health performance results of each hospital and documented wide variations between surgeons, hospitals and regions in post-CABG mortality that persist despite statistical adjustment for differences in patients case-mix. In fact, in order to control for confounding, when centres outcomes are compared, it is mandatory to take into account and control the potential effect of centres being heterogeneous with regard to variables which describe the severity of the disease for which the patient is being treated and his individual pre-operative risk.

Even though limitations of risk adjustment methods are known^[1,12,13], comparative data, especially if adjusted using a risk function derived empirically from the observed population, serve many purposes and have the potential to provide insight and lead to quality improvement.

In Italy there is no surveillance system aimed to regularly assess the outcomes of hospital care. A few isolated initiatives were made during the last decade, but they were at the regional level and involved only a limited number of hospitals^[14-16].

In early 2002 the Italian Ministry of Health, in conjunction with the National Institute of Health (ISS) launched the “Italian CABG Project” – a prospective study on short-term outcomes in patients who had CABG surgery, with the voluntary participation of the Italian Cardiac Surgery Centres. This study was the first opportunity to evaluate and publish performance indicators at the national level. It aimed at providing comparable data on observed and expected mortality 30 days after CABG intervention in each cardiac surgery centre, adjusting for pre-operative patients risk^[17,18].

This study could also give the Italian scientific community the opportunity to build and estimate a national risk function for the outcome considered, compare it to functions obtained in other countries, and use it to assess the individual pre-operative risk.

MATERIALS AND METHODS

A list of all public and private cardiac surgery centres in Italy for adult patients was prepared consulting the websites of the Italian Society for Cardiac Surgery (SICCH) and Ministry of Health.

A reference person from each centre was contacted and invited to participate in the study.

Out of the 89 adult cardiac surgery centres, 82 agreed to participate in this prospective, on-going study. Patients considered were 15-99 years old, and underwent an isolated CABG surgery (not associated with other cardiac or extra-cardiac procedures) after 1 January 2002 in one of the participating centres.

Data collection

Data collection is being carried out with standardized on-line data entry on a password protected website <http://bpac.iss.it/>.

This analysis concerns all isolated CABG interventions performed between 1st January 2002 and 30th September 2004.

List of variables and definitions

The scientific references about the choice of individual variables to be collected derive from a series of more extensive research protocols developed by the major international and national scientific societies (Society of Thoracic Surgery, American Association for Thoracic Surgery, European Association for Cardiothoracic Surgery, SICCH) and from other risk stratification protocols in

cardiac surgery developed over the last 10 years (Parsonett 1° and 2°, EuroSCORE, New York, et al.)^[5,19-22].

To define pre-operative patient risk for this study we gathered data on demographic characteristics (*gender, age, residence, and place of birth*) and on patient's health status prior to surgery. The latter included the presence of co-morbidities such as diabetes under treatment, malignant ventricular arrhythmia, cirrhosis, chronic obstructive pulmonary disease, renal failure (*dialysis or pre-operative creatinine > 2 mg/dl*), neurological dysfunction, active endocarditis, pulmonary hypertension, cancer, extra-cardiac arteriopathy and stroke; patient's haemodynamic condition (*unstable or shock*); degree of ventricular dysfunction (ejection fraction, EF, <30%; between 30% and 49%; ≥50%); previous surgery that opened the pericardium (CABG or any other interventions); unstable angina and recent infarction (< 90 days). Information on the type of intervention (CABG isolated intervention, associated with other cardiac or extra-cardiac procedures, elective or emergency, in on-pump or off-pump circulation) was also collected.

In case of death within 30 days of the intervention, date and specific cause were recorded.

Data quality assessment

Clinical Monitoring. For each participating cardiac surgery centre, a sample of records was randomly selected from the electronic archive. Independent observers, following specific standardized operating procedures (SOPs), visited each centre and compared contents of the records transmitted to those reported in the original clinical charts. These procedures allowed us to assess the reliability and completeness of the database and to maintain constant quality control.

Other controls. The completeness of data in each centre was evaluated by comparing them to hospital discharge records supplied by regional and national health information systems.

Inclusion criteria for the analytical database

Cardiac surgery centres with fewer than 100 CABG isolated interventions per year were excluded from the analytical database. Moreover, only centres that provided data continuously for at least 6 months and who had fewer than 5% of patients lost to follow-up were considered to calculate the algorithm required for the risk-adjustment procedure.

End-point and follow-up

Each cardiac surgery centre was requested to carry out an active follow-up in order to define patient's life status 30 days after CABG intervention. Then, for patients classified as lost to follow-up by the centres, life status was confirmed by consulting the local death registries.

Data analysis

Almost all risk factors were recorded as dummy variables (having or not having the risk factor); age was used as a continuous variable; ejection fraction was subdivided into 3 classes: <30%, 30-50% and 50% or more, the latter being the reference group. For this variable a "missing value" category was used.

Univariate analyses were performed on all candidate predictive variables in order to determine significant associations with the outcome.

In order to account for joint confounding the best predictive model was developed using a multiple logistic regression analysis. First, all possible confounding variables were included in the model. Second, in order to identify independent associations with the outcome, a backward stepwise method was used (exclusion probability = 0.20; inclusion probability = 0.10). A set of interaction hypotheses defined a priori was also tested.

To avoid overfitting, a cross validation procedure was applied. To this extent, patients were randomly split into two equal-size samples: sample I was used to build the predictive model (n = 17,231); sample II was used as an independent database for model validation (n = 17,079). The

entire data set was finally used in estimating the definitive coefficients and calculate their p-values, to provide more precise parameter estimates.

The Hosmer-Lemeshow chi-squared test was applied to assess the calibration (accuracy) of the risk function obtained. To evaluate the model's discriminative ability to predict individual deaths, the area under the Receiver Operating Curves (ROC) was measured. As usually reported in scientific literature, ROC values higher than 0.70-0.75 were judged as proof of a good discriminative ability.

By applying the best predictive algorithm back to each centre's data set, we estimated the expected number of deaths of that centre. The Risk-Adjusted Mortality Rate (RAMR) is then calculated by dividing, for each centre, the observed number of deaths by the expected number of deaths, and by multiplying this ratio by the average mortality rate of the whole sample. This indicator is the best estimate of what the whole population's mortality rate would be if the population had the same observed/expected death ratio of that centre.

To test heterogeneity we used a significance threshold of $p=0.05$. A RAMR significantly lower than the average mortality rate indicates that the health care provider performance is better than the average of the whole sample (low-outlier); on the contrary, a RAMR significantly higher shows a worse performance (high-outlier).

In order to analyse the effect of the loss to follow-up on risk estimate in each centre, we performed a sensitivity analysis.

All statistical procedures were performed by STATA 8.1 statistical package.

RESULTS

Out of 82 centres that agreed to participate in the study, 12 centres were excluded because the proportion of patients lost to follow-up was higher than 5% (2,878 records); 2 centres were dropped because the data collection period was less than 6 Months (87 records); 4 more centres were dropped because they performed fewer than 100 isolated CABG interventions per year (468

records). Figure 1 shows the distribution of the 64 centres that fulfilled all inclusion criteria in the 20 regions in Italy.

Of the 34,611 isolated CABG interventions performed in the 64 cardiac surgery centres, 301 patients (0.87%) were lost to follow-up and excluded from the analysis. Therefore these results refer to a database of 34,310 isolated CABG (Fig. 2).

Updated results of this study are currently available at <http://bpac.iss.it/>.

Patients characteristics and association with 30 days mortality

A detailed description of the population characteristics and univariate analysis of the association between each pre-operative variable and the 30 days mortality rate is reported in table 1.

The patients' mean age was 67.4 years, with a standard deviation of 9.42 years; 19.35% of patients were 75 or over and 20.9% were female. Among all patients, 24.5% suffered from unstable angina and 28% had an infarction within 90 days preceding the intervention, while diabetes under treatment was present in 28% of patients.

The overall crude mortality rate in the 64 centres was 2.61%, ranging from 0.33% to 7.63%. When split samples were drawn, crude mortality rates were 2.62% in sample I and 2.59% in sample II.

Most risk factors considered were significantly associated with the outcome at $p < 0.001$. Neurological dysfunction and other cardiac interventions that opened the pericardium were significant at 0.05; only endocarditis and "on/off pump circulation" were not significantly associated with 30 days mortality ($p = 0.184$ and $p = 0.835$ respectively). Emergency surgery was performed in 3.8% of patients and showed an OR of 7.22 ($p < 0.0001$). The excess of risk due to shock was 14.44 ($p < 0.0001$), while dialysis had an OR of 6.66 ($p < 0.0001$).

The multivariate predictive model, derived from logistic regression analysis, and the independent contribution of each variable to the outcome is presented in table 2. Coefficients, p-values for significant risk factors and odds ratios are reported.

Among the 23 variables considered as potential predictors, 14 were independently associated with 30 days mortality. Emergency, shock and dialysis presented the greatest odds ratios (3.89, 3.44 and 3.41 respectively, $p < 0.0001$).

To cross validate the model, the estimated coefficients from sample I were applied to both sample I and sample II. The area under the ROC curve in the validation sample was 0.80 and the Hosmer-Lemeshow test showed a chi-squared = 8.87 ($p = 0.354$).

Risk-Adjusted Mortality Rates for each centre and their 95% confidence intervals are reported in figure 2. Eight centres presented RAMRs significantly better than the national mean (2.61%) (“low-outliers”) while seven Centres exhibited significantly worse performances (“high-outliers”). There were no statistically significant differences between the RAMR of the other centres and the mortality rate of the overall population.

The sensitivity analysis considered the two extreme hypotheses, all patients lost to follow up treated as alive or dead, respectively, and did not reveal any substantial variations in the study results.

DISCUSSION

The Italian CABG Project is a voluntary, national program designed to collect and describe CABG post-operative mortality. For each participating centre, the study produces uniform mortality data, adjusted to account for differences in pre-operative risk of patients who undergo CABG surgery. This study is based on the collection of specific clinical data and allows an empirical risk adjustment function to be created and applied to the Italian study population.

Because the risk adjustment function was derived from around 34,000 CABG interventions carried out in 64 cardiac surgery centres uniformly distributed throughout the country, the algorithm constructed to standardise the comparison between hospital performances should be sufficiently stable.

In this Italian population, mortality within 30 days after CABG surgery is 2.61%. This result is very similar to those reported in other international settings, and confirms the satisfactory average level of the Italian cardiac surgery performances^[5-9].

It must be stressed that such a systematic monitoring of hospital outcomes, as well as the risk-adjusted profiling of the CABG surgery providers at national level, represents a real change for the Italian NHS. The overall mortality rate observed in this study is acceptable mainly because it has not yet been influenced by the “registry effect”, a well documented phenomenon in which improvements in performance^[10,23] are noted after the establishment of a surveillance system.

Risk adjusted mortality estimates for most of the hospitals analysed are not different from the country average. Fifty-seven of the hospitals that participated in the study performed as or better than expected, meaning their RAMRs were not statistically higher than the national mean. Only seven (about 10%) performed worse than expected, with RAMRs significantly higher than the national mean.

When we compared centres specific crude and risk adjusted mortality rates, we found small differences in most cases, and only few isolated cases suggest a case-mix of patients markedly different from the whole study population. In fact, 10 centres were classified as low outliers using unadjusted mortality rates and 8 of them were confirmed as low outliers after the adjustment; seven centres were classified as high outliers using unadjusted mortality rates, two of them had their status not confirmed in the adjusted analysis, while two other centres emerged as significantly worse than the reference mean when using RAMR. As already observed, these results show a limited impact of risk adjustment when comparing 30 days mortality after CABG, given the limited confounding effect of risk factors when comparing centers under study^[24]. In other words, the proportion of heterogeneity of mortality rates attributable to heterogeneity of distribution of risk factors between centers seems to be small.

Obviously, the classification of Centres as outliers heavily depends on the chosen threshold for statistical significance. A less conservative approach, using $p < 0.1$, would have implied three more

high outliers and three more low outliers. Widely speaking, the choice of the most appropriate threshold is not only a statistical exercise and should be based on an explicit assessment of cost and benefits associated with true and false positive and negative results of the comparison.

The “Italian CABG Project” succeeded in collecting, prospectively, specific clinical data and in building and estimating an empirically-derived Italian risk-adjustment function. In general, the meaning of risk adjustment is to control confounding. We underline that any risk adjustment function to be utilized for the purpose of comparison between centers or population must be time and population specific. This statement implies a substantial difference between “predictive models” aimed to predict the occurrence of outcome, and “explicative models” aimed to control confounding in comparison of occurrence of outcome between centers or population. Even a very valid risk score having a strong association with the concerned outcome could be irrelevant for the purpose of risk adjustment if the distribution of its values is homogeneous between centers.

Another innovative value of the Italian CABG Project is that it is the first attempt to produce outcome indicators at the national level, to profile hospitals with respect to their performances, and to publicize a report card where providers can see their own results and compare them to the Italian average.

The well known “adjusted in-hospital mortality” is a suitable indicator of the quality of assistance for many conditions, but bias can be introduced when the strategy of patients’ postoperative management is different. The “30 days mortality rate” allows for taking into account these differences and has been widely used as a valid instrument to evaluate quality of surgical centres^[11,12].

There is plenty of evidence that performance information is vital to help clinicians and hospital managers understanding where quality of care problems may exist and to target improvement efforts. Throughout the Italian CABG Project observation, overall risk-adjusted patient mortality has dropped from 2.8% in 2002 to 2.4% in 2003/04. This result cannot be underestimated and some reflections need to be made. RAMR observed in the 8 centres classified as low outliers, being

around 0.9%, could represent the best performance obtainable in our Italian population. Considering that adjusted mortality rate in 2002 was 2.8% and the best effective reduction to be expected is around 1.9%, the observed drop of 0.4% (although not statistically significant) corresponds to 21% of the best reduction effectively obtainable. To conclude, this finding should encourage hospitals and surgeons to persevere in this approach, since a valid system of quality assessment and, consequently, the hospitals critical appraisal of their own results can contribute to the improvement of performances in cardiac surgery.

The future development of a national program of profiling health care providers must be carefully designed and conducted to maximize the potential benefits and minimize the possible negative effects, for both the population and the health system, potentially associated with the publication of comparisons among providers based on outcomes^[13].

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Table 1. Characteristics of the study population and univariate association between pre-operative variables and 30 days mortality rate

	Mean	Standard Deviation	Odds Ratio	<i>p-value</i>
Age	67.4	9.40	1.07	<0.0001
	Cases	%	Odds Ratio	<i>p-value</i>
Female gender	7,143	20.90	1.46	<0.0001
Shock	361	1.06	14.44	<0.0001
Unstable haemodynamic condition before surgery	2,681	7.90	4.01	<0.0001
Diabetes	9,600	28.00	1.44	<0.0001
Malignant ventricular Arrhythmia	566	1.66	3.53	<0.0001
Cirrhosis	141	0.41	2.86	0.001
Chronic obstructive pulmonary disease	3,460	10.10	2.25	<0.0001
Dialysis	352	1.03	6.66	<0.0001
Serum creatinine >2 mg/dl	1,278	3.73	4.60	<0.0001
Neurological dysfunction	804	2.46	1.73	0.002
Endocarditis	54	0.16	2.21	0.184
Pulmonary hypertension	114	0.34	6.29	<0.0001
Cancer	434	1.27	1.82	0.010
Extra-cardiac arteriopathy	7,304	21.30	2.44	<0.0001

Stroke		1,335	3.90	1.99	<0.0001
Ejection fraction	≥50	23,772	71.17	<i>Reference</i>	
	30-49	8,713	26.10	2.49	<0.0001
	<30	917	2.75	7.23	<0.0001
	missing	908	2.65	1.22	0.400
Emergency		1,311	3.83	7.22	<0.0001
Previous CABG intervention		763	2.23	2.96	<0.0001
Any other previous surgery that opened the pericardium		403	1.17	1.97	0.003
Unstable angina		8,387	24.40	2.63	<0.0001
Recent infarction (< 90 days)		9,615	28.00	1.76	<0.0001
Off pump circulation		10,073	29.40	0.98	0.835

Table 2. Multivariate logistic regression model to predict 30 days mortality in the Study population (2002-2004)*

Patient Risk Factors	Coefficient	Odds Ratio	p-value	
Age	-0.04	0.96	0.377	
Age²	0.00	1.00	0.045	
Female Gender	0.26	1.29	0.003	
Shock	1.24	3.44	0.000	
Diabetes	0.30	1.35	0.000	
Dialysis	1.23	3.41	0.000	
Pulmonary hypertension	0.82	2.26	0.016	
Malignant ventricular arrhythmia	0.38	1.46	0.047	
Chronic obstructive pulmonary disease	0.42	1.52	0.000	
Serum creatinine >2 mg/dl	0.73	2.08	0.000	
Extra-cardiac arteriopathy	0.54	1.72	0.000	
Unstable angina	0.43	1.53	0.000	
Previous CABG intervention	1.05	2.86	0.000	
Emergency	1.36	3.89	0.000	
Ejection fraction (vs ≥ 50)	30-49	0.59	1.80	0.000
	<30	1.15	3.14	0.000
	missing	0.30	1.36	0.313
Constant	-5.24	-	0.001	

* Model predicting mortality in entire study population; ROC Area=0.80; Hosmer-Lemeshow statistic=18.08 (p=0.02). Cross-validation statistic: ROC Area=0.80; Hosmer-Lemeshow statistic=8.87 (p=0.35).

Figure 1. The number of centres included in the analytical database for each Region are indicated in red. The total number of recognised centres are written in blue and reported in brackets

Figure 2. Isolated CABG interventions performed in the 64 cardiac surgery centres that met all the Inclusion Criteria

Figure 3. Risk-Adjusted Mortality Rates for each cardiac surgery centre and their 95% confidence intervals (bars)

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APPENDIX

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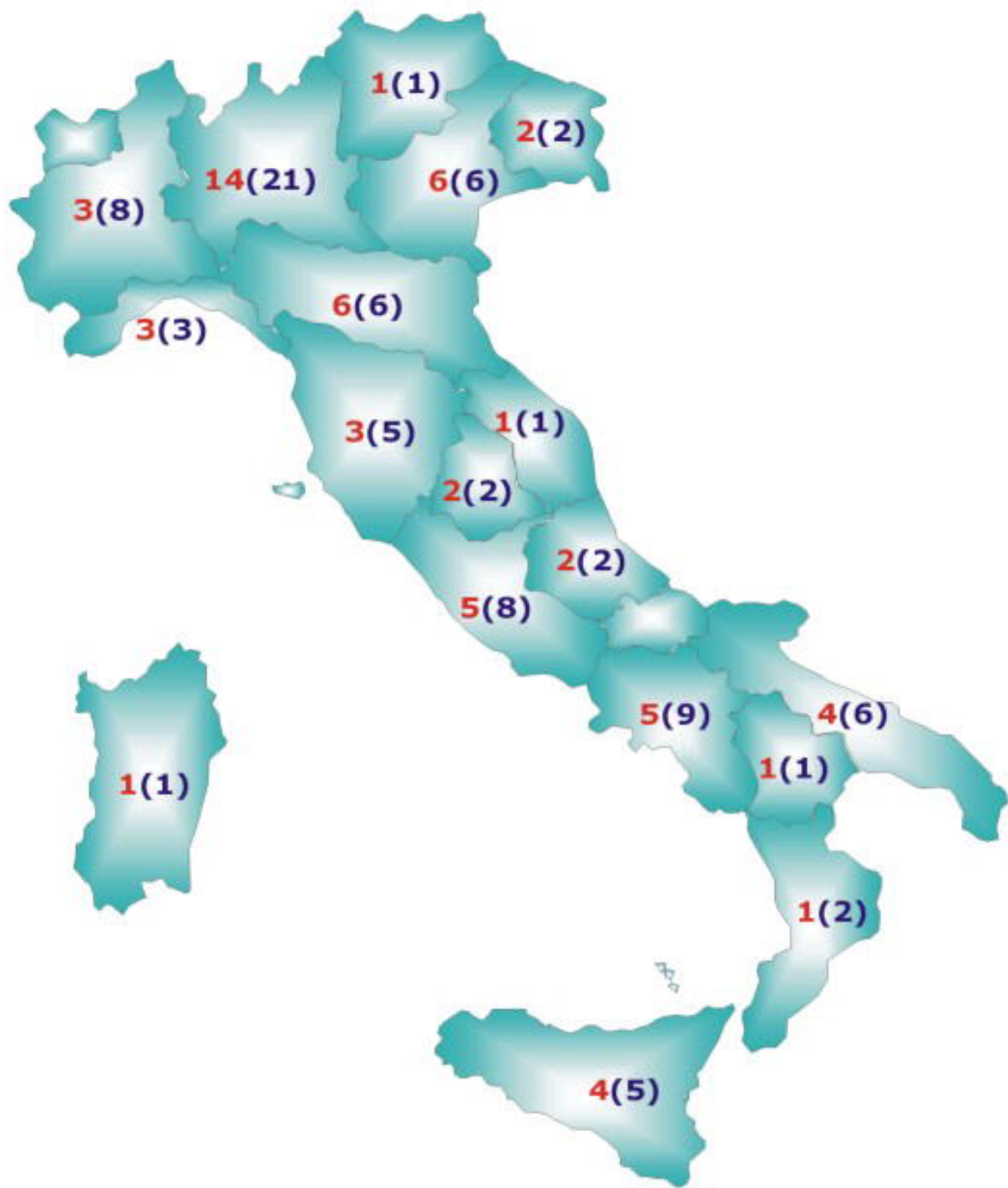
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34,611

301
(0.87%)

**LOST TO
FOLLOW-UP**

34,310

895
(2.6%)

DEAD

33,415
(97.4%)

ALIVE

RANGE 0.3%-7.6%

