The impact of the Italian law mandating an automatic external defibrillator in all sports venues on sudden cardiac arrest resuscitation rates

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In Italy, preparticipation screening (PPS) has been mandatory since 1982 and its main goal is to prevent sudden death (SD) in athletes through identification of cardiovascular diseases at risk of malignant ventricular arrhythmias in their pre-symptomatic phase. Nevertheless, some diseases can be missed by PPS: in this case, the chances of surviving a sport-related sudden cardiac arrest (SCA) depend strictly on resuscitation efforts. In 2012, the SD of two professional athletes led to the enaction of the so-called 'Balduzzi law' (D.M. 24 April 2013), which established that all sports arenas must be equipped with automated external defibrillators (AEDs) and that trained staff must be present during competitions. After some delays, the law entered into force in 2015. The study aimed at evaluating the consequences of the application of the 'Balduzzi law', calculating the incidence and rates of successful resuscitation of SCA in sports venues in the Lombardia region of Italy, before and after the application of the law.

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We collected retrospectively data regarding all SCA of presumed cardiac origin which involved both athletes and non-athletes (coaches, referees, spectators, etc.) occurring in sports venues of the Lombardia region (≈10 million inhabitants) in the period 2015-19, after the 'Balduzzi law' entered into force. The study was terminated at the end of 2019 because of the COVID pandemic. The data were compared to those collected in the period 2011–14, before the law enactment. All cases have been gathered thanks to the database built by the regional territorial emergency service (AREU) of the Lombardia region. We also consulted the news reported by the local and national press to verify that no cases were missed. As the aim of the study was to evaluate the impact of the 'Balduzzi Law', we excluded events occurring in large stadiums or arenas because the presence of onsite medical teams equipped with an AED was already compulsory when the study started. Hence, first aid to SCA victims in these places was not affected by the enactment of the law. Dichotomous variables were compared with the chi-square test and continuous variables with the Wilcoxon rank sum test. A P value < 0.05 was considered statistically significant.

Between 2015 and 2019, the incidence of SCA of presumed cardiac origin in sports venues of the Lombardia region (excluding those occurring in large arenas/stadiums) was 0.19 per 100 000 inhabitants/year (total number of events = 95), vs. 0.28 per 100 000 inhabitants/year in the period 2011–14 (total number of events = 113, P < 0.005).

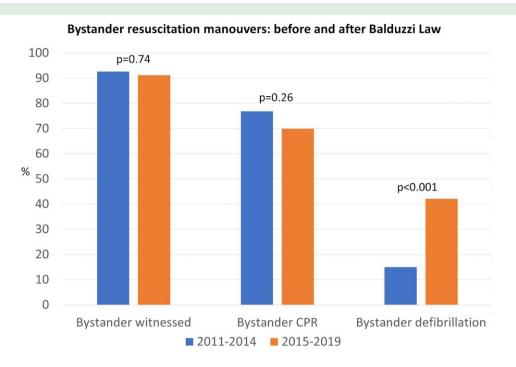
The average age of the victims was 50 years in 2015-19 vs. 52 years in 2011–14 (P = 0.96); males were 93% in the first vs. 92% in the second period (P = 1.0). Between 2015 and 2019, 56% of events took place during recreational activities, 26% during training sessions of competitive athletes, and only 16% during official competitions. No data about the location of SCA were available for the first period.

After the enactment of the 'Balduzzi law', we did not observe an increase in the rate of SCA that were witnessed by bystanders or with bystander-performed cardiopulmonary resuscitation (CPR); however, the proportion of SCA treated with AEDs increased from 15% to 42% (P < 0.001) (Figure 1). Comparing the two periods, the rate of return of spontaneous circulation (ROSC) indicative of successful resuscitation increased from 67% to 80% (P < 0.05). The association between the mandatory presence of AEDs in sports venues and resuscitation success in terms of ROSC was significant (P < 0.05). Furthermore, between 2015 and 2019 all cases of SCA with bystanderinitiated and onsite AED use were successfully resuscitated.

In more detail, the proportion of SCA among people >40 years old was 88/113 (78%) in the period 2011–14 vs. 69/95 (73%) in the period 2015–19 (P = 0.38). Overall, the rate of ROSC was 41/51 (80%) among people ≤40 years old vs. 111/157 (71%) among people > 40 years old (P = 0.17) (Figure 1). Resuscitation was successful in 80% of males vs. 83% of females (P = 0.35).

In Italy, the overall incidence of SCA of presumed cardiac origin is around 50/100 000 inhabitants/year, while SCA in sports venues in the Lombardia region was 0.19/100 000 inhabitants/year in the period 2015–2019, with a decreasing trend compared to the previous four years. This figure is exactly the same as that was estimated by a previous study based on the press reports of SCA in Italy in 2015.³ According to these data, we can estimate that only ≈1 case in every 250 SCA of presumed cardiac origin occur in sports venues, mostly in male individuals older than 40-year-old who are usually amateur athletes or nonathletes. The low prevalence of SCA in young competitive athletes may be explained by the low prevalence of cardiac diseases (particularly in women) and the systematic PPS that is mandated by Italian law, which entails periodical sports medicine examinations. Another interesting observation is that only a minority (16%) of SCAs occurred

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Successful resuscitation/total number of events: before and after Balduzzi Law

Age classes (years)	< 30	30-39	40-49	50-59	60-69	>70	Total
Before compulsory AED law (2011-2014)	9/13 (69%)	8/12 (67%)	14/22 (64%)	15/20 (75%)	24/32 (75%)	6/14 (43%)	76/113 (67%)
After compulsory AED law (2015-2019)	19/20 (95%)	5/6 (83%)	10/12 (83%)	21/27 (78%)	8/10 (80%)	13/20 (65%)	76/95 (80%)

Figure 1 Top: percentages of individuals who suffered from cardiac arrest of presumed cardiac origin before (2011–14) and after (2015–19) the enactment of the law mandating the presence of an automated external defibrillator and trained personnel in sports venues who were bystander-witnessed, rescued with bystander cardiopulmonary resuscitation, and with bystander use of an automated external defibrillator. Bottom: percentages of individuals who were successfully resuscitated/total number of cardiac arrests during the two study period.

during official competitions, while the remaining happened during training or recreational activities. Although the 'Balduzzi law' mandated the presence of an AED in sports venues only during competitions, the law was amended in 2021 and now an onsite AED must always be present.

Previous data showed that up to 90% of sport-related SCA cases receiving AED shock before Emergency Services arrival survived hospital discharge. ^{5,6} In our study, we observed that early AED use on top of bystander CPR was always followed by ROSC. This may be explained by the fact that substrates underlying SCA during sport such as cardiomyopathies or coronary artery disease most often cause arrhythmic ('shockable') SCA, as opposed to SCA occurring in the general population that is often non-shockable. Moreover, victims of SCA in sports arenas are usually young adults with no ventricular dysfunction in whom early defibrillation is usually successful. ⁷

In conclusion, our study suggests that enactment of a Law mandating the presence of an AED and trained personnel in sports venues was associated with more frequent and effective bystander defibrillation and

with a higher probability of ROSC. We must acknowledge that the study was performed only in the out-of-hospital setting and we lack inhospital and long-term outcome data. Moreover, because data collection started in 2011, the study considered two periods with different duration.

Author contributions

Alessandro Zorzi and Guido Francesco Villa contributed to the conception and design of the work. Guido Francesco Villa, Marco Botteri, and Giuseppe Stirparo contributed to the acquisition, of data for the work. Alessandro Gianni, Giulia Mattesi, and Alessandro Zorzi contributed to the analysis, or interpretation and Alessandro Gianni drafted the manuscript. Alessandro Zorzi critically revised the manuscript. All gave final approval and agreed to be accountable for all aspects of work ensuring integrity and accuracy.

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Conflict of interest: None declared.

Data availability

The data that support the findings of this study are available from the corresponding author, A.Z., upon reasonable request.

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