

The PROFID project

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The **PROFID** project

A large European effort towards personalized prediction and prevention of sudden cardiac death after myocardial infarction funded by the European Union

Sudden cardiac death (SCD) is the leading cause of death and accounts for ~20% of all deaths. In most cases, it is a consequence of myocardial infarction. The advent of the implantable cardioverter-defibrillator (ICD) represents tremendous progress in the prevention of SCD. As shown in landmark trials, the ICD reduces mortality if implanted prophylactically in patients with a severely impaired left ventricular ejection fraction.^{1,2} This is due to the fact that a reduced left ventricular ejection fraction after myocardial infarction is a risk marker not only for total mortality but also specifically for sudden cardiac death.³

Therefore, current guidelines recommend routine implantation of ICD for primary prevention of SCD in patients with ejection fraction \leq 35%.⁴ Although this practice has saved many lives, it has significant shortcomings:^{5,6}

- 1. Due to a whole series of advances in the management of heart failure and coronary artery disease, the risk of SCD in heart failure has decreased significantly in the last 15 years.⁷ Thus, only a minority of these patients that receive an ICD for primary prevention of SCD will ever receive an appropriate ICD therapy over the lifetime of the device.⁸ Although in most patients the ICD will never be needed, all patients carry the considerable long-term risk of complications associated with the device.^{9,10}
- 2. The majority of SCD cases in absolute numbers do not occur in patients with severely reduced ejection but in the low-risk patients with moderately reduced or preserved ejection fraction.^{11,12} The explanation for this seemingly paradoxical observation is the far larger number of patients that belong to the low-risk group of patients with ejection



Figure I Geographic location of the PROFID consortium partners. The countries where the consortium partners are located are depicted in darker colour.

fraction >35%. The need to identify those patients that carry a high individual risk among this, in general low-risk group has been repeatedly stated, but the search for appropriate ways to accomplish this has been futile.¹³

Thus, it is clear that we need a radically new approach to risk stratification for SCD, away from the simple dichotomy approach based on the ejection fraction towards a personalized assessment of the *individual* risk. This would allow us to avoid the many unnecessary ICD implantations in patients with ejection fraction \leq 35% and at the same time protect the patients with ejection fraction >35% that carry a high individual risk by targeted CD implantation. Such an approach would however require a radically new methodology.

This personalized approach is exactly the goal of the PROFID project (https://profid-project.eu/). PROFID is funded by the European Union over the Horizon 2020 programme and consists of two steps:

- The analysis of existing evidence from a large variety of different data sources including national registries of post-infarction patients, registries of primary prevention ICD registries, electronic health records, and claims databases. These data will be analysed by a combination of traditional statistical methods and machine learning techniques and will result in the development of a clinical prediction model for the assessment of the individual risk for SCD.
- The proof of the utility of this prediction model in clinical practice and in particular for the decision for ICD implantation by conduction of two large randomized clinical trials in patients with previous myocardial infarction:
 - The PROFID-Reduced trial in patients with ejection fraction ≤35% but a *low* predicted individual risk for SCD that will be randomized to ICD vs. no-ICD in a non-inferiority design.
- PROFID-Preserved in patients with EF>35% and a *high* predicted individual risk for SCD that will be randomized to ICD vs. no-ICD in a superiority design. The total number of patients in both trials will be \sim 3920. The results of the trials will show whether this personalized approach can be successfully applied across the whole range of ejection fraction for the decision whether to implant an ICD for primary prevention of SCD or not.

In parallel, health economic analyses will assess the economic impact of this novel approach on health care systems.

In PROFID, all major stakeholders are represented: academic institutions with top expertise in SCD, patient organizations, large hospital chains, a large statutory health insurance company, policymakers, and state authorities across Europe (*Figure 1*). Importantly, the European Society of Cardiology is a key consortium partner and represented by the European Heart Rhythm Association.

In summary, PROFID has the clear ambition to advance clinical practice and to introduce a disruptive innovation in the personalized prevention of SCD (*Figure 2*).



Figure 2 Ideal result of PROFID. On the left, the unsatisfactory current situation of imprecise identification of patients that should receive an implantable cardioverter-defibrillator based solely on the ejection fraction. On the right, the ideal result of the PROFID project: an optimal identification of high-risk patients that can be successfully protected from sudden cardiac death by implantable cardioverter-defibrillator implantation. OMT, optimal medical therapy.

References

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COVID-19 pandemic: a sentiment analysis

A short review of the emotional effects produced by social media posts during this global crisis

Ever since the first headline reporting the coronavirus disease 2019 (COVID-19) outbreak in December 2019, social media has served as a breeding ground for the contagion of information about the novel coronavirus. The information, a potpourri of truth and lies, has exploded across various social media platforms, outpacing the spread of the disease. A social media pandemic has preceded the disease pandemic, stirring a diversified spectrum of emotions. While the world has witnessed pandemics before, all were in the pre-social media era. The effect of social media during such an unprecedented pandemic crisis has yet to be identified.

The assembling of information vs. misinformation, trust-building vs. fear-mongering, and anger vs. comfort are a few of the sentiments reverberating in the social media pandemic. In the new reality of social distancing and self-quarantined lockdown, Twitter has emerged as a paramount platform for crisis communication, with a COVID-19-related tweet every 45 ms.¹ We computed a sentiment analysis of tweets, retweets, and replies with #COVID19 over the 2-week

period, from March 17-30, 2020, to analyse the perception of the COVID-19-related information across social media.

We used the Twitter application programming interface (API) to record a sample of 10 000 tweets, retweets, and replies with a #COVID19 hashtag. Tweets, retweets, and replies were restricted to English language only for the analysis. The twitteR package was used to search tweets with the help of the standard Twitter API. The Syuzhet package in R was used for the sentiment analysis.² The nrc sentiment lexicons of the tidytext package were used to assign scores for the positive/negative sentiment, and for possible emotions such as anger, fear, and trust. The nrc sentiment lexicon categorizes words in a binary fashion into categories of positive and negative, which were further categorized into mutually non-exclusive sentiments such as anticipation, anger, disgust, joy, fear, surprise, sadness, and trust. Statistical analysis was performed using R version 3.6.2.

A total of 1 400 000 tweets were analysed. Despite the unprecedented global health crisis, the tweets demonstrated a trend toward