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The ESC DAPT Guidelines 2017

The first-ever ESC Guidelines Focused on DAPT are discussed by Marco Valgimigli

The scope of the 2017 European Society of Cardiology (ESC) focused update on dual antiplatelet therapy (DAPT) in coronary artery disease (CAD) developed in collaboration with the European Association for Cardio-Thoracic Surgery (EACTS), which is published in this issue of the journal, is to address recommendations on DAPT in patients with CAD. This is the first focused update issued by the ESC, and it follows shortly on the American College of Cardiology (ACC)/American Heart Association (AHA) guideline focused update on duration of DAPT released in 2016.

The need for such a document has been voiced by the community on multiple occasions, and it stems from the apparent conflicting results arising from available studies and limited evidence on various patient subsets, in whom the trade-off between benefits and risks of DAPT may differ from that observed in the more selected patient cohorts included in trials.

The publication of the 2017 focused DAPT update corresponds to the 21st anniversary of the publication of the first randomized clinical trial establishing the superiority of DAPT over anticoagulant therapy among patients undergoing percutaneous coronary intervention.

Based on over 35 randomized clinical trials, including more than 225 000 patients, DAPT is among the most intensively investigated treatment options in the field of cardiovascular medicine. Hence, we do not lack studies; rather we struggle to reconcile their results with respect to the implications for clinical practice. The main difficulties in undertaking this exercise are that a DAPT regimen (i.e. including type and duration), which may be beneficial for a given patient, may at the same time be potentially harmful for another one.

It is sobering that while cardiology and cardiologists has/have had at least some resistance in embracing the concept of personalized medicine under the dogma *keep it simple and consistent*, the evidence generated around DAPT type and duration has clearly paved the way for a major paradigm shift in the field of cardiology. The traditional belief that one drug at a consistent dose is recommended (i.e. a class I recommendation from guidelines) for virtually all patients can no longer meet the expectations of the cardiovascular community which nowadays seeks for treatment options, which cure the disease and are associated with negligible side effects.

While indisputably effective in mitigating non-fatal ischaemic events, long-term DAPT for all patients does not meet these requirements. This should not dismiss the value of this contemporary treatment option; but rather remind the clinicians that the risks and benefits need to be thoroughly assessed in a dynamic fashion in each single patient over time.

When reading the ESC focused update on DAPT, please keep in mind three key points.

(1) An individualized DAPT prescription is a concept to which at least in principle, cardiologists today are largely in agreement; yet, how this should be translated into practice remains challenging. The reasons

for this difficulty come from the fact that studies focusing on selected patient populations are scarce, and those which did, have been frequently interpreted outside the context in which the data has been generated. The consequences are, that the quality of the evidence for carefully selected patient subsets is low, despite results that are frequently more convincing and sound. The ESC DAPT focused update task force has attempted to provide the best possible interpretation of currently available data for DAPT in various patient populations. Yet, clear gaps in evidence can only be filled by personal judgement and institutional guidelines.

- (2) The exact wording associated to each given recommendation is of utmost importance. Recommendations around DAPT go from class I (i.e. must do) to class III (i.e. do not do) through class IIa (i.e. should do) and IIb (i.e. may do), depending on the patient population and the setting of presentation. They should not be interpreted outside the recommended context that were set forth.
- (3) Dual antiplatelet therapy is by all means a secondary prevention therapeutic regimen and not only a regimen to prevent coronary stent thrombosis. While acknowledging that DAPT was purposely developed to prevent the thrombotic occlusion, there would probably be no reason to prescribe this treatment beyond a few months after coronary stent implantation today, if the only value would be the prevention of a recurring stent occlusion.

A few final words on some novelties introduced by this document.

As long as, we agree that each drug is unique in terms of pharmacokinetics, pharmacodynamics, clinical benefit, and side effects, why should a stent, which releases a drug, not fulfil the same paradigm?

There is today convincing evidence that DAPT requirements differ after the first vs. second generation DES. While first generation DES should no longer be used, it remains likely that vulnerability to short DAPT regimens may similarly differ among the so-called second or third generation DES and even more after *bioresorbable stent* implantation. While not always possible or desirable, stent-specific DAPT evidence and recommendations should be ideally implemented.

The ESC focused update on DAPT has decided not to provide stent-specific recommendations to avoid any possible industry bias and to reinforce the concept that, as stated before, long-term DAPT regimens should be viewed as a therapeutic means to protect the patient more than the stent. Yet, only a few coronary devices have provided at least partially convincing safety data in patients treated with short term DAPT; no study has so far investigated specific DAPT regimens in a controlled setting in individuals in whom the risks of long DAPT regimens potentially outweigh the benefits, such as those at high and very high bleeding risk. Whenever possible and applicable however, credit has been given to the few devices which have provided controlled data after short-term DAPT regimen.

Finally, a major breakthrough offered by this document is that short-term DAPT is no longer a justification for preferring bare metal over drug-eluting stents on the background that clear superiority of the

latter over the former has been consistently shown, also in patients receiving short- (3–6 months) and ultra-short (1 month) DAPT duration after stent implantation.

If the ESC mission is to reduce the burden of cardiovascular disease, the mission statement of the ESC 2017 focused update on DAPT is to assist the community in interpreting and applying into practice the large body of evidence around DAPT type and duration in patients with CAD. With this delivery in mind, an extraordinary task force, which I had the privilege to chair, and to which I would like to extend my deepest appreciation and gratitude, has worked for more than 24 months. With that respect, the case-based implementation of the 2017 ESC focused update on DAPT in CAD is an additional unique feature of this document. I invite you to read this companion document, where, for the very first time, the task force provides critical commentaries upon real cases submitted by

practitioners across the globe. To them, I would like to extend my gratitude for having responded to our call as well as acknowledge many of them whose clinical cases could not finally be accepted.

The 2017 ESC focused update on DAPT in CAD hopes to have adequately served the community with a scientific sound and practice-oriented document on use and possible misuses of DAPT in patients with CAD.



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HEART Group meeting

The 2017 HEART Group meeting of cardiovascular research editors took place at the ESC Congress in Barcelona on 28 August 2017

Editors of cardiovascular journals, although in friendly competition, have similar problems and questions and are eager to hear what their colleagues think about many issues related to their work. For that purpose, the *HEART Group* was founded several years ago and regularly meets at the *European Society of Cardiology Annual Congress* for a breakfast meeting. All editors of cardiovascular journals are invited, and a significant number usually attend.

At the 2017 meeting, several issues were intensely discussed ethical challenges as well as the assessment of reviewer quality, a crucial issue for a journal of excellence.

Ethical issues

Proper scientific publishing is the backbone of the scientific process. (EHJ, 33, 557–561, 2012 <https://doi.org/10.1093/eurheartj/ehr506>) The editor-in-chief of the *European Heart Journal* Prof. Thomas F. Lüscher reported that an increasing number of allegations had been received by the *European Heart Journal* during the last years and therefore, he had inaugurated an ESC Journal Family Ethical Committee chaired by Prof. Maarten Simoons from Rotterdam together with Prof. Kim Fox from the Imperial College in London, Prof. Christian Hamm from the



2017 HEART Group Meeting in Barcelona