Guidelines for PCI

Evidence-based recommendations for coronary interventions, accompanying medications and drug-releasing stents

The European Society of Cardiology (ESC) has issued guidelines for percutaneous coronary interventions (PCI). What is the background of these guidelines and which consequences will they have from a practical standpoint? Gabriela Eriksen spoke to Sigmund Silber, M.D., Professor for Cardiology at the Ludwig-Maximilian University in Munich and Board Member and Treasurer of the ESC.

Hospital Post: Prof. Silber, what is new in the ESC PCI Guidelines?

S. Silber: The ESC has, for the first time, developed guidelines for PCI. New, in particular, is the outstanding critical evaluation of the flood of randomized studies.

In comparison with the German guidelines, what are the fundamental differences, for instance, for acute coronary syndrome?

S. Silber: One difference is in the preparation process of the document: Unlike Germany, the ESC has additional external experts – in the case of the PCI guidelines, 17 persons reviewed the document, which was prepared by the 13 members of the PCI Task Force and approved by the additional 13 members of the general guidelines committee. The guidelines are backed by three ESC presidents (the former, the present and the future). Thus, in all, 43 internationally recognized experts support the recommendations.

In the case of an acute coronary syndrome without ST segment elevation, there are no striking differences – we have specified the accompanying medication somewhat more. When you compare the flow diagrams of the German and the European guidelines, you will notice that we do not speak of "the glycoprotein IIb/IIIa inhibitors" in general, but rather more closely specify the substances depending upon type of application. We also preferably recommend unfractionated ("old") heparin and have more reservations for the low molecular weight heparins, especially enoxaparin. For clopidogrel, we have left out the "asterisk" and recommend the fastest possible administration, regardless of whether or not a by-pass operation is planned.

For which points is there now clarity – for example, "when lysis, when PCI – or when DES … and when not?"

S. Silber: In contrast with the German guidelines, we have subdivided the first 12 hours after the beginning of the symptoms into less than three hours and from three to twelve hours. In comparison with primary PCI, thrombolysis can save a reasonable amount of heart muscle mass only during the first three hours. After three hours, primary PCI is superior to thrombolysis.

Prof. Dr. Sigmund Silber, M.D., F.A.C.C., F.E.S.C., Chairman of the European PCI Guideline Commission

Could the ESC guidelines be applied to Germany "one-to-one" or is there a need for adjustment?

S. Silber: Precisely in Germany the ESC PCI guidelines could be transferred one-to-one. This applies especially to STEMI due to the relatively high density of heart catheter laboratories and the numerous already existing networks. In particular, these networks could be used for the recommended "post-thrombolysis PCI," the routine heart catheter examination carried out on a PCI standby basis – also after successful (!) thrombolysis. A regional adaptation is not required. After all, 40 of the 49 ESC member states have already adopted the PCI guidelines one-to-one and have refrained from preparing their own guidelines.

Have the stent studies, which were presented at the ACC 2005, already provided new impulses for a future revision?

S. Silber: Our task force will continually observe the development in the coming years and make an update when it becomes apparent that evidence-based practice relevant changes in the previous recommendations are necessary. We were very critical in our analysis of the currently available data for the PCI guidelines. For high evidence levels, conducting a randomized study was not alone sufficient. We attached great importance on a primary clinical end point because we do not want to perform coronary cosmetics but rather improve the patient's clinical progress. Beyond this, data from multicenter studies are more meaningful than that from a single study center. For example, the Sirtax study had, in fact, a primary clinical end point, but was limited by its single study center character. Reality and Scandstent were, indeed, multicenter studies, but they lacked a clinical parameter as the primary end point. In this respect, one must first wait for the results from additional randomized multicenter studies with primary clinical end points instead of making hasty conclusions that later cannot be substantiated with evidence. Medicine and, particularly, cardiology, is full of examples of false conclusions that were drawn too quickly based upon subgroup analyses lacking validity.

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