PRESS RELEASE

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Anticoagulants in Patients with Congenital Heart Defects

Largest study worldwide points out risks with NOACs

Berlin, November 17, 2020 - One in eight patients with congenital heart defects is dependent on anticoagulants. But taking them is associated with risks. A new study conducted by the Competence Network for Congenital Heart Defects recommends more careful use of the novel oral anticoagulants.

The intake of so-called Non-Vitamin K oral anticoagulants (NOACs) must be closely monitored. Photo: © iStockphoto.com, AlinaTraut

Cardiac arrhythmia, heart failure, heart valve diseases, and vascular occlusion due to blood clots: According to a current long-term study carried out by researchers of the University Hospital of Münster at the Competence Network for Congenital Heart Defects in cooperation with Barmer health insurance, one in eight patients in Germany with a congenital heart defect receives blood-thinning and anticoagulant drugs to reduce the risk of complications or even death. However, taking these drugs can lead to problematic side effects and interactions with other medication.

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NOACs are also on the Rise in Patients with Congenital Heart Defects

For a long time, patient with congenital heart defects were mainly treated with so-called vitamin K antagonists (VKAs). These active ingredients, known under the trade names Warfarin® or Marcumar®, prevent the formation of certain clotting factors produced by the liver. However, their application is made more difficult by numerous interactions during the breakdown of the substance by the body's own enzymes. These medications require regular coagulation monitoring, as they interact with foods containing vitamin K and various drugs.

The expectations for the novel oral anticoagulants (NOACs) such as Eliquis®, Pradaxa®, Lixiana® and Xarelto® were all the higher. These antithrombotic drugs have been available on the market since 2010. Unlike VKAs, they inhibit certain coagulation factors directly and thus act more quickly. There is no need for regular coagulation monitoring. The interactions are limited to other active ingredients that influence blood clotting. Bleeding is one of the most frequent side effects.

World's Largest Study Urges Caution

Since the new anticoagulants have become available, their use in patients with congenital heart defects has steadily increased.
According to this study, the proportion of NOACs in the anticoagulants prescribed for patients with congenital hearts defects was already 45 percent in 2018. But caution is advised. Recognized randomized controlled trials have so far only proven positive results and properties of NOACs compared to VKAs in acquired cardiovascular disease. The effects in congenital heart defects, on the other hand, have not yet been researched.

On the basis of anonymized data from the German Barmer Health Insurance, the research group led by cardiologist and EMAH specialist Paul Gerhard Diller from the University Hospital of Münster has investigated the correlations between anticoagulation therapy and complications and deaths occurring over the long term in around 44,000 patients and determined the risks more precisely. The study, which is unique in its scope worldwide, proves that the risks associated with taking NOACs are significantly higher in

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patients with congenital heart defects due to their anatomical and physiological peculiarities as compared to patients with acquired heart diseases. "Taking NOACs is associated with higher risks than previously assumed," said Gerhard-Paul Diller.

The Longed-for Alternative Can Become a Deadly Trap

Patients with congenital heart defects who received NOACs experienced more frequent vascular occlusions due to blood clots, bleeding, arrhythmia, and heart failure in the first year of treatment and were more likely to die than patients treated with VKA preparations.

A similar picture emerges in the long-term observation of the relationship between treatment plans and diagnoses. "The fact that the coagulation status does not need to be monitored in NOACs means that patients are not monitored closely enough," said Gerhard Paul Diller. In light of these study results, it should be thoroughly investigated whether VKAs should be considered instead of the long-desired alternatives in patients with congenital heart defects. In addition, treatment with NOACs should be accompanied by specialized cardiologists at appropriate centers.

The study was funded by the EMAH Foundation Karla Völlm. It is part of the OptAHF research project, which is supported by the Innovation Fund of the Joint Federal Committee G-BA.

For Your Research

The results of the study within the research project OptAHF were published under the title "Current use and safety of novel oral anticoagulants in adults with congenital heart disease:
Results of a nationwide analysis including more than 44,000 patients" in the European Heart Journal.
https://pubmed.ncbi.nlm.nih.gov/33184662/

More about the Innovation Fund of the Federal Joint Committee G-BA funded research project OptAHF: https://www.kompetenznetz-ahf.de/en/researchers/research/ongoing-studies/optahf-improvement-of-care/

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