CORE-MD

Coordinating Research and Evidence for Medical Devices

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Press release
Lack of published evidence for high-risk medical devices in Europe – new findings from the CORE-MD project

Investigators from the CORE-MD Project revealed at the end of August in the European Heart Journal that a majority of new high-risk medical devices that are used to treat heart disease have been released to the market in the European Union (EU) with insufficient evidence from clinical trials. That means that too little information about the safety and performance of new implantable devices is available for healthcare professionals to make informed decisions on patient care.

In a thorough study of 71 different devices from 7 types that are implanted to treat coronary heart disease, heart valve disease, and abnormal heart rhythms, investigators in the European CORE-MD project systematically searched the scientific literature for publicly available reports of prospectively designed trials. They reviewed in detail 308 clinical trials that had been reported between 2000 and 2021, involving 97,886 individual subjects. They collected evidence from trials that had been published in medical papers before and after each device had been approved by EU regulators.

The most reliable clinical evidence for a medical intervention comes from randomised controlled trials (RCT) but no single RCT had been published for any of the devices that were reviewed, by the date of its market release in Europe. The majority of all investigations (81%) were prospective non-randomized clinical trials, that have an increased risk of bias due to inherent limitations. For 30% of the approved devices, no published report could be identified in the medical literature either before or after its date of market access.

The devices that were evaluated in this study had been approved under the provisions of the previous EU Directive on medical devices, that was replaced in 2017 by the new Regulation (EU 2017/745). In future, a summary of clinical evidence for each high-risk medical device will be made available in a document known as the SSCP (Summary of Safety and Clinical Performance), but its publication will not abolish the responsibility of investigators and manufacturers to ensure that full results of all studies are published promptly in peer-reviewed scientific journals.

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There appear to be double standards for the approval of new treatments in Europe. Before a new drug can be approved by the European Medicines Agency, an RCT is expected whereas this study from the CORE-MD consortium indicates that the situation with medical devices has been quite different during the past two decades.

Senior author of the study, Professor Stephan Windecker, Chairman of the Department of Cardiology at Bern University Hospital, Inselspital, Professor of Cardiology and Vice-Dean at the Medical Faculty of the University of Bern (Switzerland), said: "Larger and better-designed clinical trials of high-risk devices need to be conducted and reported more quickly. More specific EU guidance on clinical trial methodologies, appropriate endpoints, comparators, and follow-up is required, and systems need to be developed to demonstrate concordance of regulatory judgements between Notified Bodies".

Scientific coordinator of the CORE-MD project on behalf of the European Society of Cardiology, and Chairman of the Regulatory Affairs Committee of the Biomedical Alliance in Europe, Professor Alan Fraser, said: "It is impossible to practise evidence-based medicine unless all results from clinical trials are publicly available. Every patient needs reassurance that any recommendation from their doctor that a medical device should be implanted, will be based on sound evidence. Publication and transparency are essential to establish trust between the patient and doctor".

The results were reported by Professor Stephan Windecker in a late-breaking session at the Congress of the European Society of Cardiology in Amsterdam on 28th August 2023 and published simultaneously in the European Heart Journal[1].

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For more information, contact: Valentina Tageo, Project Manager, core-md@escardio.org

[1] Siontis G. and coauthors / DOI: 10.1093/eurheartj/ehad567

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