Heart study finds faulty link between biomarkers and clinical outcomes

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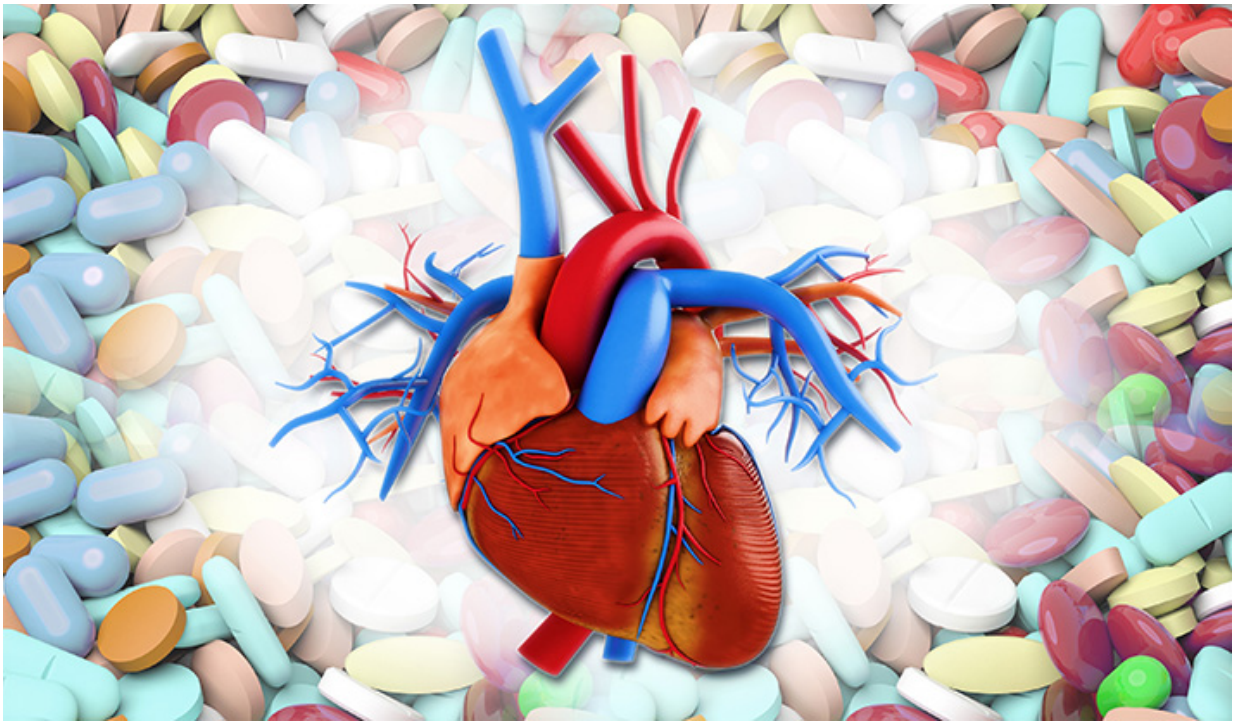

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Surrogate endpoints (biomarkers), which are routinely used in clinical research to test new drugs, should not be trusted as the ultimate measure to approve new health interventions in cardiovascular medicine, according to a recent study by Yale School of Medicine researchers in *JAMA*.

Biomarkers generally refer to diseases, symptoms, and signs during clinical trials that are associated with other, more complicated diseases and symptoms (clinical outcomes).

In the Yale study, lead author and internal medicine resident at Yale School of Medicine Dr. Behnood Bikdeli and his colleagues examined the potential disconnect between biomarkers and clinical outcomes by screening prior publications in the field of cardiovascular medicine. They found that although the surrogate endpoint trials published in the highest-impact journals frequently demonstrated high effectiveness of the tested drug, less than one third of them had a clinical outcomes trial of the drug for the same purpose published.

Additionally, when there was a subsequent clinical outcomes trial, approximately half failed to validate the positive impact of the drug on the biomarker. Bikdeli notes that while the new findings only apply to the field of cardiovascular medicine, doctors and researchers in other fields, such as oncology, hold similar reservations about using biomarkers to approve new drugs.

More information: Behnood Bikdeli et al. Two Decades of Cardiovascular Trials With Primary Surrogate Endpoints: 1990–2011, *Journal of the American Heart Association* (2017). DOI: 10.1161/JAHA.116.005285

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