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Guidance for Sponsors
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Echocardiography: Advantages in Clinical Trials

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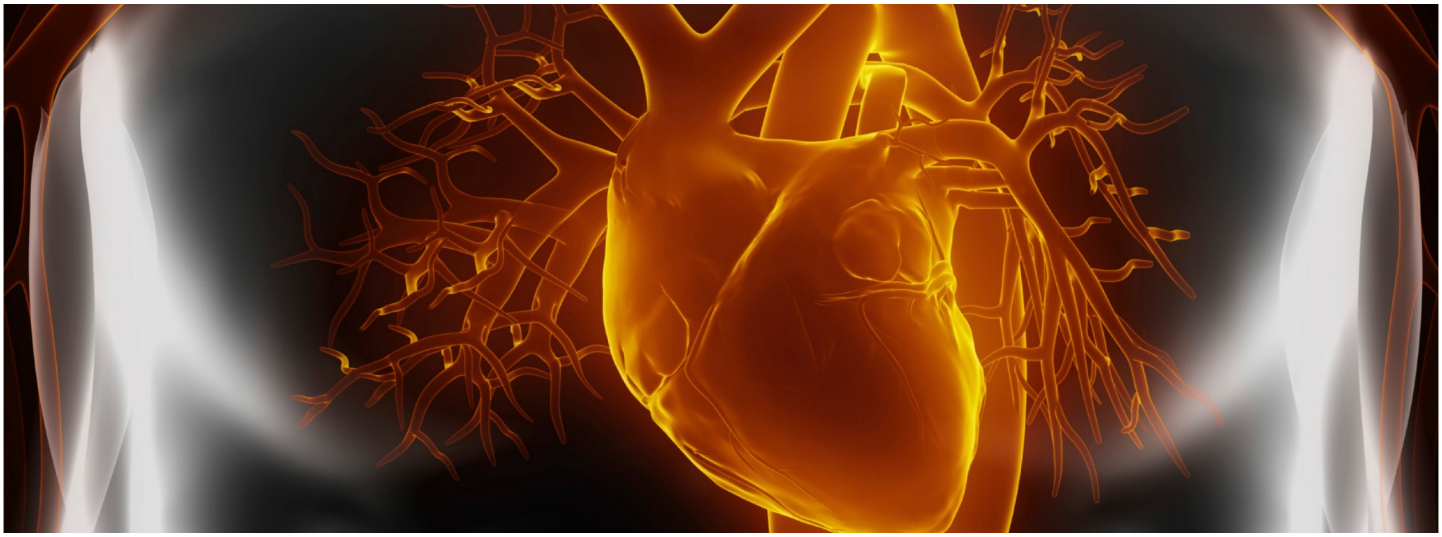

Echocardiography is safe, portable, affordable and available worldwide, which makes it one of the most practical imaging tools for clinical trials. It measures chamber size, function, valves and mass, and changes in these measures predict major cardiovascular events, allowing smaller trials and earlier answers. Since the first edition of this issue, global longitudinal strain and three-dimensional echocardiography have become standard measures, and cardio-oncology guidelines now define cardiac injury from cancer therapy partly by strain. Standardized acquisition and core-lab reading remain essential.

Echocardiography

Echocardiography uses ultrasound to create real-time moving images of cardiac structure and function, offering a noninvasive way to evaluate the effect of therapies on the heart. It carries no radiation risk, the equipment is portable and affordable, and studies can be performed almost anywhere, allowing broad trial populations. Images can be transmitted electronically for remote post-processing and interpretation, which makes echocardiography well suited to standardized reading by a core laboratory.

Trials use echocardiography to assess chamber size, systolic and diastolic function, valve function and myocardial mass, and as a surrogate marker of prognosis. Adverse remodeling, declining ejection fraction and changes in diastolic function or mass are linked to major adverse cardiovascular events such as stroke, myocardial infarction, heart failure and death. Measuring these changes allows conclusions before clinical events occur, and positive remodeling and improved ejection fraction can demonstrate therapeutic success. The precision of echocardiographic measurement allows smaller trials.

In clinical practice, ventricular dimensions and volumes are measured in every patient to assess valvular disease, myocardial infarction, cardiomyopathy and congenital heart disease. These values yield the ejection fraction, which guides prognosis and treatment. Left ventricular mass, indexed to body surface area, helps distinguish causes of hypertrophy. Serial measurement shows the effect of medical and surgical therapy, and the absence of change can indicate lack of response.

Standardized Methods

Standardized methods are essential to reduce intra- and interobserver variability, and the ASE and EACVI chamber quantification recommendations remain the reference.[1] Dimensions should be indexed to body surface area. Left ventricular dimensions are measured with 2D imaging in the parasternal long-axis view. Volumes are measured with the biplane method of disks (modified Simpson's rule) in apical four- and two-chamber views and used to calculate ejection fraction; where image quality allows, three-dimensional volumes are more accurate and reproducible. Typical measurements include left ventricular

end-diastolic volume index (LVEDVI), end-systolic volume index (LVESVI), mass index (LVMI) and ejection fraction (LVEF).

Doppler echocardiography measures blood and tissue velocities from frequency shifts. It grades valvular stenosis and regurgitation, assesses diastolic function and myocardial relaxation, and helps evaluate pericardial disease.

Speckle-tracking strain tracks the natural acoustic pattern of the myocardium to measure deformation. Global longitudinal strain (GLS) detects subclinical dysfunction before ejection fraction falls and improves the sensitivity and specificity of stress testing for coronary disease. Automated software has made strain far faster to measure. The 2022 ESC cardio-oncology guidelines define asymptomatic cancer therapy–related cardiac dysfunction partly by a relative decline in GLS of more than 15% from baseline, and recommend 3D ejection fraction and GLS where available.[2] Vendor differences in strain values make consistent equipment and software especially important in trials.

Limitations and Contrast

Ultrasound must travel to the heart and back, so image quality is affected by body habitus, ribs, lung tissue, calcification and devices such as pacemaker leads or mechanical valves. Positioning, probe selection and ultrasound-enhancing agents can overcome many of these limits. These FDA-approved intravenous contrast agents improve endocardial border definition, increase the accuracy of 2D measurements and augment Doppler signals, and can be used safely in most patients.

Guidance for Sponsors

Using echocardiography in a trial

- **Follow guideline methods.** Specify ASE/EACVI chamber quantification methods and indexing in the imaging charter.[1]
- **Prefer 3D and strain where feasible.** Use 3D volumes and GLS for greater reproducibility and earlier detection of change.[2]
- **Keep vendor and software consistent.** Strain values differ between platforms; scan each patient on the same system throughout.
- **Train and certify sonographers.** Standardize views, frame rates and acquisition at every site.
- **Use contrast when windows are poor.** Define criteria for ultrasound-enhancing agents in advance.
- **Read centrally and blinded.** A core lab with a small, consistent reader group minimizes variability.

Summary

Echocardiography is a globally available technology that is safe to repeat. Serial measurements can show the effect of a therapy over days, months or years, and using echocardiographic surrogate endpoints can reduce trial size compared with clinical outcomes such as stroke or death. With strain, 3D imaging and standardized core-lab reading, echocardiography remains a pillar of evidence in cardiovascular and cardio-oncology trials.

About the Author

Dr. Kevin E. Steel, D.O., F.A.C.C., a cardiologist, wrote the original edition of this issue for Intrinsic Imaging. He graduated from Kirksville College of Osteopathic Medicine in 1999, completed his cardiovascular disease fellowship at Wilford Hall Medical Center at Lackland Air Force Base, and completed an advanced cardiac imaging fellowship at Brigham and Women's Hospital, Harvard Medical School, in 2007. He has held numerous academic appointments, has spoken nationally and internationally on cardiac imaging, and has published extensively in the field. He is board-certified and Level III trained in echocardiography, cardiac CT, cardiac MRI and nuclear cardiology.

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About Intrinsic Imaging, LLC

Intrinsic Imaging is an ISO certified medical imaging CRO and imaging core lab providing comprehensive services in support of Phase I-IV clinical trials and Class I, II, III medical device trials. Intrinsic Imaging is also a world leader in conducting Artificial Intelligence studies. With its team of more than 650 board-certified and fellowship-trained physicians, Intrinsic Imaging's team has sub-specialization in all therapeutic areas, including Cardiovascular, Central Nervous System,Gastroenterology, Musculoskeletal, Oncology and Ophthalmology. Certified by the British Standards Institution (BSI), Intrinsic Imaging is the only company in the world to hold five ISO certifications specifically for providing imaging core lab services on clinical trials. For more information, please visit www.IntrinsicImaging.com.

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