Medical Policy Manual

Topic: Acoustic Cardiography

Section: Medicine

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IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Acoustic cardiography is a technique that simultaneously records the electrical and acoustical aspects of the heart. By integrating the acoustic and electric properties, acoustic cardiography is intended to enhance the diagnostic ability of simple auscultation. The information from acoustic cardiography has also been used to optimize hemodynamic parameters for device placement, particularly with cardiac resynchronization therapy (CRT).

Acoustic cardiography utilizes 3 inputs: a single electrocardiogram (EKG) lead from 2 standard electrodes, and 2 audio sensors placed at the usual V3 and V4 positions on the chest.[1] These 3 channels synchronously record electrical and audio information. The audio information is processed using wavelet signal processing techniques and a diagnostic algorithm that filters out extraneous noise and uses time-frequency analysis to objectively define the heart sounds and the intervals between sounds. An analogue visual display of the audio data is then displayed and paired with the electrical data from the EKG recording.

Output from acoustic cardiography can generate numerous parameters, some of which may have clinical applicability.[1] Three of these measures are:

- S3 strength—a quantitative measure of the intensity of the S3 heart sound, which is an abnormal

sound that is associated with systolic dysfunction
- Electromechanical activation time (EMAT), defined as the interval between the onset of the QRS complex and the closure of the mitral valve. EMAT is the main parameter that is used to optimize CRT therapy by choosing the interval that optimizes cardiac output
- Left ventricular systolic time (LVST)—the interval between mitral valve closure and aortic valve closure. This length of the LVST has been correlated with changes in ejection fraction.

Auscultation

Auscultation for an S3 is part of the physical exam when evaluating for presence of heart failure. The presence of an S3 indicates systolic dysfunction and is a specific physical exam finding supporting systolic heart failure. The S3 is an indistinct sound that can be difficult to hear and is not present in all patients with systolic dysfunction. Systolic dysfunction can be confirmed by echocardiography and/or other imaging modalities.

Optimization of CRT

Optimization of CRT is usually done using Doppler echocardiography.[2] Optimization involves manipulation of the atrio-ventricular (AV) and interventricular (VV) pacer settings in order to maximize left ventricular (LV) filling and stroke volume. Some evidence has reported that optimization improves overall clinical benefit, but these data are not uniform. Also, the question of whether re-optimization should be performed following initial optimization is controversial, as is the timing of re-optimization if it is performed.

Regulatory Status

The following systems have received 510(k) marketing approval from the U.S. Food and Drug Administration (FDA):

- The Audicor® (Inovise Medical Inc.)
- The Zargis Acoustic Cardioscan™ (ZAC) (Zargis Medical Corp.)

MEDICAL POLICY CRITERIA

Acoustic cardiography is considered **investigational** for all indications including, but not limited to diagnosis of heart failure and for optimization of hemodynamic parameters in patients treated with a cardiac resynchronization therapy device.

SCIENTIFIC BACKGROUND

Published literature has evaluated the use of acoustic cardiography in two areas:

- As an aid in the diagnosis of heart failure
- For optimization of hemodynamic parameters in patients with a cardiac resynchronization therapy (CRT) device.

Components of the diagnostic evaluation for heart failure include a variety of clinical symptoms and physical exam findings such as dyspnea, orthopnea, pulmonary rales, increased jugular venous pressure, and peripheral edema. Routine diagnostic evaluation for heart failure also includes measurement of brain natriuretic peptide (BNP) and other common laboratory measures, and a chest x-ray. A direct measure of ejection fraction by echocardiography, nuclear medicine imaging, or other imaging modalities is a crucial component of clinical evaluation for heart failure. In a clinical area such as heart failure, where multiple tools to predict risk already exist, randomized comparative clinical trials comparing outcomes of patients testing with versus without acoustic cardiography are needed to demonstrate impact on health outcomes, such as quality of life, and heart failure-related morbidity or mortality.

Where acoustic cardiography is proposed for use in optimization of hemodynamic parameters in patients with a CRT device, randomized controlled trials are needed comparing health outcomes of patients diagnosed with Doppler echocardiography versus acoustic cardiography.

Acoustic Cardiography for Diagnosis of Heart Failure

There are no studies of clinical utility of acoustic cardiography for diagnosis of heart failure. The following studies are examples of available literature on the technical feasibility or diagnostic accuracy of acoustic cardiography for diagnosis of systolic dysfunction in patients with suspected heart failure:

- Michaels et al. evaluated whether acoustic cardiography improved detection of S3 and S4 in 90 patients referred for angiography.[3] A total of 35 subjects at various levels of clinical experience, from medical student to attending, listened to recordings of each patient's heart sounds using auscultation alone, and then auscultation with acoustic cardiography. The gold standard for the presence or absence of heart sounds was the consensus of 2 experienced readers who were blinded to other aspects of the study.

  There was improvement in the ability to detect S3 in each cohort of clinical training, with overall accuracy improving by between 2-18%. The improvement in accuracy was statistically significant for more experienced trainees but not for medical students. For example, using auscultation alone, residents detected an S3 correctly in 68% of patients. This improved to 85% when auscultation was combined with acoustic cardiography. For attending physicians, the accuracy of S3 detection was 72% with auscultation alone, and this was improved to 80% ($p<0.01$) with the addition of acoustic cardiography. Nevertheless, interpretation of results from this study is limited by the lack of a comparative treatment group.

- Maisel et al. evaluated the predictive ability of acoustic cardiography for acute heart failure in 995 patients 40 years and older who presented to the emergency department with dyspnea.[4] The main parameter used was the strength of the S3 sound graded on a 0-10 scale. The gold standard for the diagnosis of acute heart failure (AHF) was consensus by two cardiologists who were blinded to the results of acoustic cardiography. For the entire population, the S3 strength was predictive of AHF in univariate analysis but was not an independent predictor in multivariate analysis. For the subpopulation of patients who were labeled as 'gray zone' patients based on an intermediate level of BNP (100-499 pg/mL), the information from acoustic cardiography improved the diagnostic accuracy of AHF from 47-69%. Another potentially problematic subgroup examined was obese patients (body mass index [BMI] >30), in whom auscultation is often more difficult. In this population, the sensitivity of S3 detection improved from 14-28% with the addition of acoustic cardiography, but the specificity decreased from 99-88%. Maisel and colleagues published a secondary analysis subsequent to this publication which analyzed the significance of S3 sounds in other sub-populations, but concluded that overall, S3 was not a significant predictor of AHF in a multivariate model when accounting for other measured parameters (such as race, ECG findings, x-ray and BNP levels).[4] These results do not support the use of acoustic cardiography as an independent predictor of heart failure in the general group of patients presenting to the emergency department with dyspnea and point to the need for additional study of patient selection criteria.

- Kosmicki et al. compared the diagnostic accuracy of acoustic cardiography with brain natriuretic peptide (BNP) in 433 patients who had results from acoustic cardiography, BNP, and echocardiography.[5] Echocardiography was used as the gold standard for the diagnosis of systolic dysfunction. When compared to BNP alone, acoustic cardiography was more accurate in diagnosing systolic dysfunction (area-under-the-curve [AUC] 0.88 vs. 0.67, respectively; $p<0.0001$). When confined to patients with BNP levels in the indeterminate range, acoustic cardiography also outperformed BNP in diagnosing systolic dysfunction (AUC 0.89 vs. 0.64, respectively; $p<0.0001$). Nevertheless, because the diagnosis of heart failure consists of several steps, study of acoustic cardiography should be conducted within the established diagnostic hierarchy to quantify the effect of this testing within standard medical practice.

- Wang et al. evaluated the ability of acoustic cardiography to distinguish between patients who had heart failure with systolic dysfunction (n=89), heart failure with normal systolic function (n=94), and hypertension without clinical heart failure (n=109).[6] All patients underwent acoustic cardiography and echocardiography, and the diagnostic accuracy of acoustic cardiography was compared to echocardiography. For distinguishing patients with hypertension from patients with heart failure and normal systolic function, the sensitivity of acoustic cardiography was 55%, the specificity was 90%, and the area under the curve was 0.83. For distinguishing heart failure and normal systolic function from heart failure with systolic dysfunction, the sensitivity of acoustic cardiography was 53%, the specificity was 91% and the area under the curve was 0.81. These values were not significantly different from echocardiography for any of the measures reported.

In summary, acoustic cardiography may improve the accuracy of detection of an S3 heart sound, although this finding has not been consistent in all subgroups examined. Acoustic cardiography has not been demonstrated to be an independent predictor of the diagnosis of acute heart failure when combined with other relevant clinical information. In order to demonstrate an incremental benefit in the diagnosis of heart failure, the improvement in diagnostic accuracy with and without acoustic cardiography must be in the context of the entire spectrum of clinical information collected routinely in the workup of a patient with suspected heart failure. For example, two studies report that acoustic cardiography improves the accuracy of heart failure diagnosis for patients with a “gray zone” BNP. However, a gray zone BNP does not necessarily mean the diagnosis of heart failure is uncertain when all clinical information is considered; therefore, this type of evidence is not sufficient to conclude that acoustic cardiography improves the diagnosis of heart failure.

Acoustic Cardiography for Optimization of Hemodynamic Parameters in Patients with a CRT Device

The following studies reported on acoustic cardiography for optimization of hemodynamic parameters in patients treated with a cardiac resynchronization therapy (CRT) device:

- Toggweiler et al. reported that optimization of CRT settings by EMAT resulted in improved measures of clinical and hemodynamic factors such as work capacity, maximum oxygen uptake, ejection fraction, and end-systolic volume.[7] However, this study did not compare EMAT with Doppler echocardiography and thus does not offer relevant data on this question.

- Zuber et al. reported the correlation of optimal atrio-ventricular (AV) and interventricular (VV) intervals, as determined by echocardiography and acoustic cardiography in 43 patients with a CRT device.[8] There was a high correlation for the optimal AV delay intervals (r=0.86, p<0.001) and a moderate correlation for the VV delay intervals (r=0.58, p<0.05). These authors also reported that the test-retest reproducibility was higher for the EMAT method (r=0.91) than for echocardiography (r=0.35) and that the intraobserver variability was similar for EMAT versus echocardiography (9.9% vs. 8.5%, respectively).

- Hasan et al. reported the correlation of acoustic cardiography and echocardiography for optimization of CRT in 22 subjects.[9] The correlation between the overall values as determined by each method was high (r=0.90, p<0.001). In the majority of patients (77.3%), the values obtained from echocardiography and acoustic cardiography were within 20 msec of each other. The authors also reported that acoustic cardiography took less time to perform and was easier to interpret.

- Taha et al. also evaluated the correlation of acoustic cardiography with echocardiography for optimization of CRT settings, using the parameter of S3 signal strength rather than EMAT. There was a high correlation between the 2 parameters for optimization of AV delay (r=0.86, p<0.001) and a somewhat lower correlation for optimization of VV delay (r=0.64, p<0.001).[10] For VV delay, the optimal intervals were identical in 56% of patients, and for VV delay the optimal intervals were identical in 75% of patients.

- Zuber et al. evaluated the agreement in optimal AV and VV values using a number of different optimization methods in 20 patients treated with a CRT device.[11] The different methods included various sequencing of Doppler echocardiography and EMAT parameters. There was poor agreement between the different methods of optimization, and there was not one method that was clearly preferable to the others.

In summary, there is a high correlation between optimization of CRT settings by Doppler echocardiography and acoustic cardiography using EMAT values. EMAT may be simpler and easier to perform compared to Doppler echocardiography. However, it is extremely unlikely that clinical centers performing CRT optimization would not have expertise in performing echocardiography for this purpose. There is no evidence that health outcomes are improved when using acoustic cardiography for optimization compared to echocardiography.

Clinical Practice Guidelines

No evidence-based clinical practice guidelines were identified which recommend the use of acoustic cardiography for any indication.

Summary

<u>Acoustic Cardiography for Diagnosis of Heart Failure</u>

A number of published articles support that acoustic cardiography improves the detection of an S3 heart sound compared with auscultation alone. However, there is no evidence that acoustic cardiography contributes independent predictive information when added to a standard clinical workup for heart failure that includes physical exam findings, laboratory testing, and routine imaging studies. Therefore the use of acoustic cardiography as an aid in the diagnosis of heart failure is investigational.

Acoustic Cardiography in Patients with a Cardiac Resynchronization Therapy (CRT) Device

When used to optimize CRT settings, several studies report that acoustic cardiography has a high correlation with Doppler echocardiography. However, no studies have demonstrated that acoustic cardiography is superior to echocardiography for this purpose, and therefore there is no evidence that acoustic cardiography improves outcomes when used for optimization of CRT therapy. The use of this type of a device in patients with a CRT device is therefore investigational.

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12. BlueCross BlueShield Association Medical Policy Reference Manual "Acoustic Cardiography." Policy No. 2.02.27

CROSS REFERENCES

None

CODES	NUMBER	DESCRIPTION
CPT	0223T	Acoustic cardiography including automated analysis of combined acoustic and electrical intervals; single, with interpretation and report
	0224T	Acoustic cardiography, including automated analysis of combined acoustic and electrical intervals; multiple, including trended analysis and limited reprogramming of device parameter - AV or VV delays only , with interpretation and report
	0225T	Acoustic cardiography including automated analysis of combined acoustic and electrical intervals; multiple, including trended analysis and limited reprogramming of device parameter - AV or VV delays , with interpretation and report
HCPCS	None	