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Horizon Scanning Technology Prioritising Summary

Acoustic cardiography for the diagnosis of heart failure

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PRIORITISING SUMMARY

REGISTER ID: 000514

NAME OF TECHNOLOGY: ACOUSTIC CARDIOGRAPHY

PURPOSE AND TARGET GROUP: FOR THE DIAGNOSIS OF HEART FAILURE

STAGE OF DEVELOPMENT (IN AUSTRALIA):

- | | |
|---|---|
| <input type="checkbox"/> Yet to emerge | <input type="checkbox"/> Established |
| <input type="checkbox"/> Experimental | <input type="checkbox"/> Established <i>but</i> changed indication or modification of technique |
| <input checked="" type="checkbox"/> Investigational | <input type="checkbox"/> Should be taken out of use |
| <input type="checkbox"/> Nearly established | |

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- | | |
|---|-------------|
| <input type="checkbox"/> Yes | ARTG number |
| <input checked="" type="checkbox"/> No | |
| <input type="checkbox"/> Not applicable | |

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
USA	✓		
Switzerland	✓		

IMPACT SUMMARY:

A specialised acoustic cardiography system such as the AUDICOR TS¹ manufactured by Inovise Medical, Inc (United States) may be used to detect the presence of the S3 heart sound. In patients with suspected heart failure, the detection of the S3 heart sound in conjunction with other diagnostic tools in an emergency setting may increase the accuracy of heart failure diagnosis.

BACKGROUND

Heart failure (HF) is a common condition with an incidence and prevalence that increases with age. HF occurs when heart function is impaired causing the heart to pump blood less efficiently around the body. HF may be caused by a number of

¹ The AUDICOR TS is not registered on the ARTG

diseases or conditions including hypertension, ischaemic heart disease or cardiomyopathy. Symptoms of severe heart failure include chronic tiredness and dyspnoea or shortness of breath at rest or on exertion (AIHW 2010a; Chronic Heart Failure Guidelines Expert Writing Panel 2006). Systolic HF, where the heart fails to effectively contract in systole, is the most common cause of chronic HF. Diastolic HF, which is more common in the elderly, retains systolic function and is indicated by the impairment of left ventricle filling during diastole (Chronic Heart Failure Guidelines Expert Writing Panel 2006).

Diagnosis of heart failure is usually based on clinical features, chest x-ray, objective measurement of ventricular function by echocardiography and an electrocardiogram (ECG). A diagnosis of HF *cannot* be ruled out by the presence of a normal chest X-ray. In addition an ECG is seldom normal and abnormalities are frequently non-specific. However, an echocardiogram can distinguish between systolic dysfunction (typically a left ventricular (LV) ejection fraction <40%) and normal resting systolic function, associated with abnormal diastolic filling. The echocardiogram can also detect correctable causes of chronic HF, such as valvular disease. However, echocardiography is considered expensive and may not be readily available in all emergency centres. In addition, plasma levels of B-type natriuretic peptide (BNP) may have a role in diagnosis, primarily as a *rule out*, rather than rule in diagnostic test (Chronic Heart Failure Guidelines Expert Writing Panel 2006). An inverse relationship between the sensitivity and specificity for heart failure diagnosis exists for BNP values. High and low values of BNP are easily interpreted, however intermediate values in the so-called “grey-zone” between 100-50 pg/ml are considered problematic (Maisel et al 2010; Zuber et al 2007).

Cardiac auscultation usually involves using a stethoscope to listen to a patient’s heartbeat. Healthy adults have two normal heart sounds: the first heart sound (S1) made by the closing of the atrioventricular valves, and the second heart sound (S2) made by the closing of the semilunar valves. The third heart sound (S3) may be present in younger individuals and some athletes, however it is usually absent by the time adults reach middle age. The presence of the S3 later in adult life may indicate the failure of the left ventricle to fill as in cases of dilated congestive heart failure. The S3 occurs at the beginning of diastole after S2 and is lower in pitch than S1 or S2 as it is not of valvular origin and is thought to be caused by the oscillation of blood back and forth between the walls of the ventricles initiated by movement of blood from the atria (Figure 1) (Wikipedia 2010).

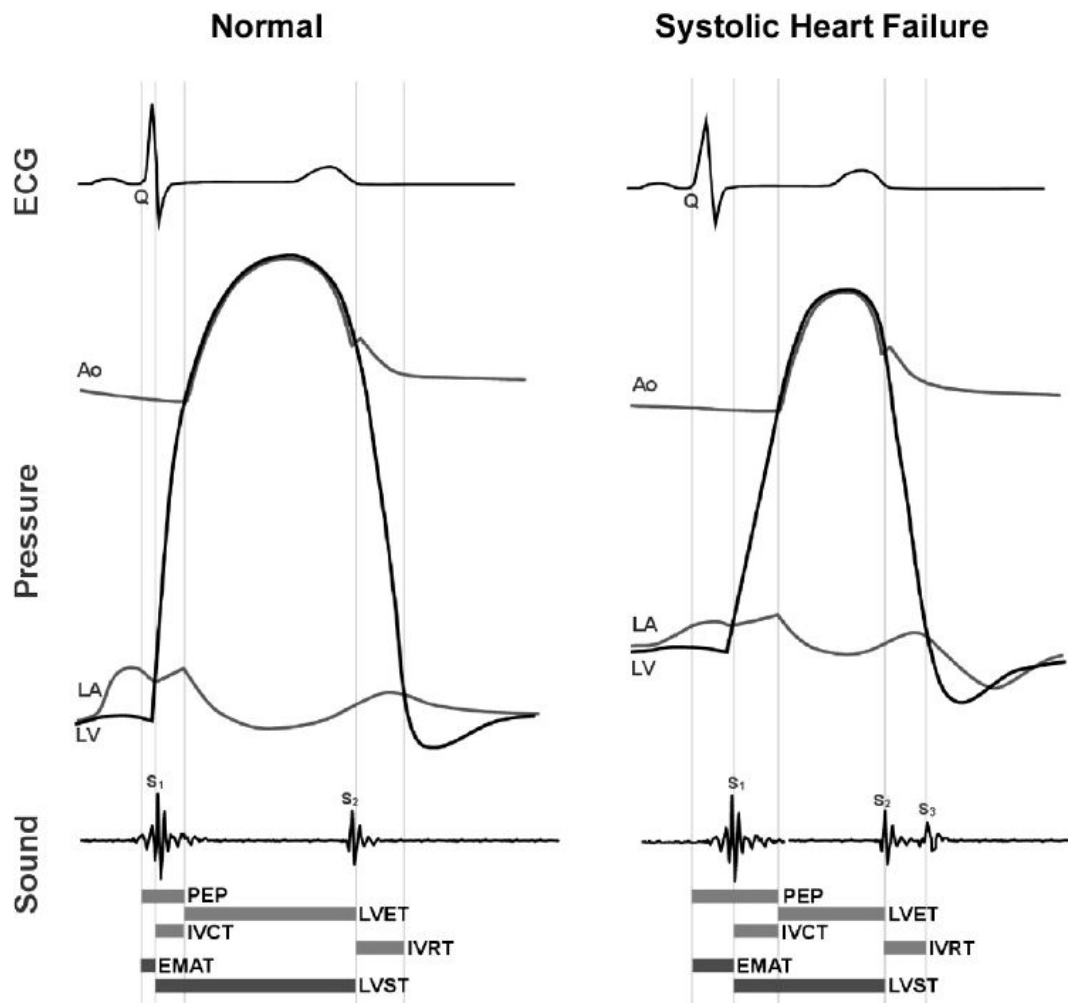


Figure 1 Normal and systolic heart failure sound data obtained by the AUDICOR device. PEP = pre-ejection period, LVET = left ventricular ejection time, IVCT = isovolumic contraction time, IVRT = isovolumic relaxation time, EMAT = electromechanical activation time, LVST = left ventricular systolic time (Peacock et al 2006a)

The early diagnosis and treatment of HF may result in better clinical outcomes, however misdiagnosis of acute heart failure is estimated to occur in 10-20 per cent of cases in emergency departments. It has been suggested that acoustic cardiography may be used to detect the presence of the third heart sound (S3) and in so doing increase the diagnostic accuracy of BNP in patients with suspected HF who fall into the BNP grey-zone (Figure 2) (Maisel et al 2010). In addition, S3 may prove to be a useful tool in the diagnosis of HF in obese patients as diagnostic BNP levels vary considerably in this patient group (Daniels et al 2006).

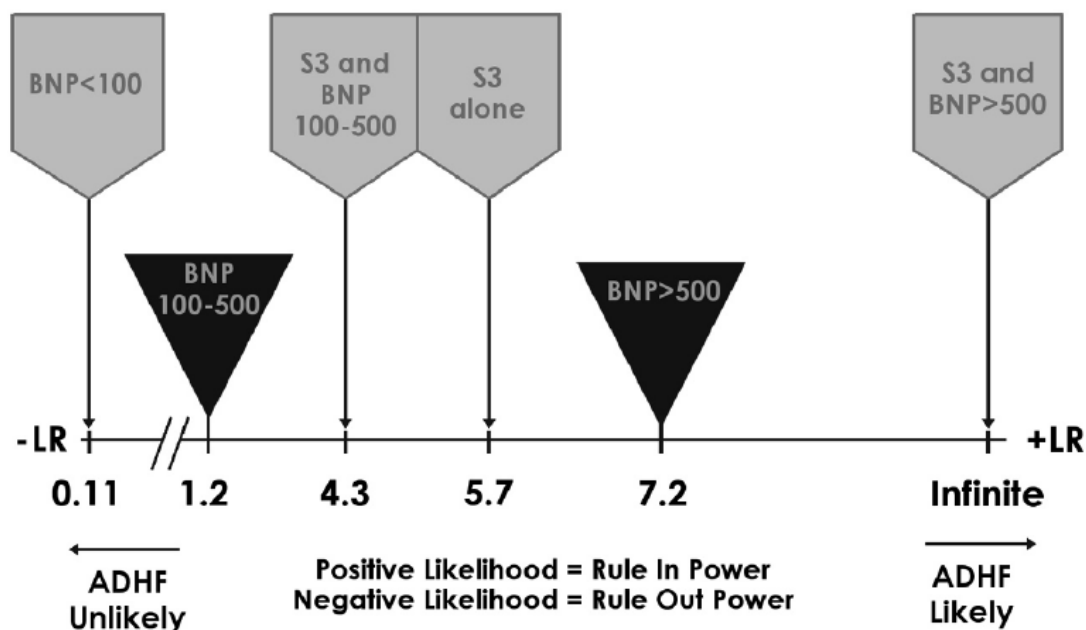


Figure 2 The diagnostic pathway using BNP and S3 heart sounds for patients suspected of heart failure (Peacock et al 2006a)

Specialised equipment does exist for the detection of the S3 heart sound including the AUDICOR TS, a portable acoustic cardiograph or the AUDICOR 200 for hospital based diagnosis, both manufactured by Inovise Medical, Inc (USA). Although the S3 heart sound can be heard with the bell-side of the stethoscope (auscultation), used for lower frequency sounds, it is best detected using a device like the AUDICOR, an ECG accessory which replaces the standard V3 and V4 leads on the ECG with sensors that collect sound and electrical data (Figure 3). Collected data are analysed using an algorithm to identify the presence of S3. This can occur at the bedside in the same time span as that taken to obtain a 12-lead ECG and a print out can be obtained (Maisel et al 2010).



Figure 3 Placement of the AUDICOR device with the acoustic V3 and V4 leads (printed with permission Inovise Medical, Inc)

At least one study has reported on the use of the S4 heart sound, which occurs when atrial contraction rapidly distends the ventricle, for the diagnosis of heart failure in patients undergoing left heart catheterisation (Gupta & Michaels 2009).

CLINICAL NEED AND BURDEN OF DISEASE

Based on 2007-08 NHS self-reports, 277,800 Australians or 1.4 per cent of the population had HF failure or oedema, with females reporting a higher disease prevalence (1.7%) than males (1.0%). Prevalence of HF increased with age from 2.6 to 8.2 per cent in people aged 55-64 and >75 years, respectively. Although HF was the attributable cause of death in 4,055 individuals in 2007, due to the complex nature of the disease it was also listed as the underlying or associated cause of death in 19,967 cases. The majority of deaths occurred in people aged over 75 years. The age-standardised death rate for heart failure and cardiomyopathy (associated and underlying cause) is higher for males than for females at 99.2 deaths per 100,000 population compared with 72.4 for females. However, this rate has declined over time with a 26 per cent reduction in the age-standardised death rate for heart failure between 1998 and 2007. Heart failure is the fifth leading cause of death for females and is the 10th leading cause of death for males, representing 3.5 and 2.3 per cent of all deaths, respectively (AIHW 2010a).

The use of pharmaceutical agents may give an indication as to the number of patients who may progress to HF. ACE inhibitors may delay the development of symptomatic CHF in patients with asymptomatic LV dysfunction and beta-blockers when administered early post-myocardial infarction may reduce the subsequent development of CHF in patients with preserved ventricular function. In addition, anti-hypertensive medication may reduce blood pressure and reduce the incidence of CHF (Chronic Heart Failure Guidelines Expert Writing Panel 2006). During 2007-08 in Australia, 3.8 million patients filled in excess of 70 million PBS-subsidised prescriptions for medicines to prevent or treat cardiovascular disease, an increase of 8.2 per cent over the period 2004-05. During this period 838,427 patients had 5.8 million prescriptions for beta-blockers dispensed, 2 million patients filled 20.8 prescriptions for ACE inhibitors and 173,854 patients had 846,068 prescriptions dispensed for anti-hypertensive medication (AIHW 2010a).

In the year 2007-08 there were 45,212 public hospital separations for the principal diagnosis of heart failure (ICD-10 code I50), with an average length of stay of 7.6 days. The overwhelming majority of these separations were for individuals aged over 70 years of age (36,187 or 80%) and for those individuals with congestive heart failure (34,999). The number of public hospital separations has remained steady over the past 10 years (AIHW 2010b).

In New Zealand there were 7,734 public hospital discharges for heart failure during the year 2006-07, with an average length of stay of 17.8 days. There were slightly

more discharges for males than females (4,051 vs 3,683), however the average length of stay for females was considerably longer than that for males (23.4 days vs 12.8 days). The total number of discharges included 1,189 for individuals of Māori origin and 469 were of Pacific Islander origin (Ministry of Health 2010).

DIFFUSION

The AUDICOR is no longer marketed in Australia, however it may re-enter the Australian market within 3-5 years (personal communication Inovise Medical, Inc).

COMPARATORS

As described in the Background section, the diagnosis of heart failure is usually based on clinical features, chest x-ray, objective measurement of ventricular function by echocardiography and an electrocardiogram (ECG). A diagnosis of HF cannot be ruled out by the presence of a normal chest X-ray and an ECG is rarely normal. An echocardiogram can distinguish between systolic dysfunction (typically a left ventricular (LV) ejection fraction <40%) and normal resting systolic function, associated with abnormal diastolic filling. In addition, plasma levels of B-type natriuretic peptide may have a role in diagnosis, primarily as a rule out, rather than rule in diagnostic test. Right heart catheterisation to measure ventricular function is considered the gold standard for the diagnosis of diastolic HF, however this may not be practical in all patients, especially those presenting in an emergency department. (Chronic Heart Failure Guidelines Expert Writing Panel 2006). In 2006/2007, the [Medical Services Advisory Committee](#) recommended public funding for the use of B-type natriuretic peptide (BNP) assays for the diagnosis of heart failure in the hospital emergency setting. This report found that there was direct high-level evidence that the time to discharge and treatment and the number of hospital and intensive care admissions were reduced in most symptomatic patients who received BNP-assisted diagnosis to *rule out* HF, compared to conventional assessment.

SAFETY AND EFFECTIVENESS ISSUES

A large, multi-centre study, the HEARD-IT² trial (7 sites in the United States, and 1 site in Switzerland and Taiwan each) enrolled adult patients (>40 years) presenting to the emergency department with dyspnoea. After an initial examination, including patient history, an ECG and BNP testing, patients were classified by the treating physician as to their probability of having HF. Readings from the acoustic cardiography, collected by the AUDICOR device, were then taken into account by the physician and the diagnosis was re-evaluated in light of these results. A further re-evaluation of the diagnosis was conducted using all laboratory and radiographic results (level III-2 prognostic evidence). Two cardiologists assessed the results

² HEARD-IT trial = Heart failure and Audicor technology for the Rapid Diagnosis and Initial Treatment

independently and any disagreements were assessed by a third cardiologist (Collins et al 2009).

A total of 1,036 patients were enrolled, however 81 patients were excluded due to a lack of acoustic cardiography or reference standard results. In 39 of the 70 patients without an S3 result (55.7%) the recording was too poor to be used and the remaining 31 patients had a heart rate exceeding 115 beats/minute. Of the remaining 995 patients (median age 63 years, range 40-95 years), 413 (41.5%) were diagnosed as having HF on the basis of the reference standard. Agreement on the reference standard diagnosis between cardiologists was good at 94.5 per cent ($\kappa = 0.901$, 95% CI [0.876, 0.926]). Using the results of S3 alone, 233/995 (23.4%) of patients were diagnosed with HF, resulting in a sensitivity, specificity and overall accuracy of 40.2, 88.5 and 68.4 per cent, respectively when compared to the reference standard. In comparison, physician auscultation with a stethoscope performed poorly, identifying 65 patients with HF, with a sensitivity, specificity and overall accuracy of 14.6, 97.7 and 64.9 per cent, respectively. The values for accuracy of diagnosis (when HF is considered an 80% certainty) for the physical examination alone, acoustic cardiography alone, physical examination combined with S3 and then at discharge with all diagnostic information considered are summarised in Table 1. The use of S3 either alone or in conjunction with physical examination did not significantly improve the accuracy of diagnosis. S3 was highly specific, therefore patients without heart failure could confidently be ruled out, but its low sensitivity indicates that it cannot be used as a diagnostic, rule in tool alone. Accuracy only increased when all diagnostic information was available to the treating clinician. Of concern is the high number of false negatives when any method of diagnosis was used.

Table 1 Accuracy of diagnosis for heart failure

	Physical exam alone (%) [95% CI]	S3 alone (%) [95% CI]	Physical + S3 (%) [95% CI]	At discharge (%) [95% CI]
Accuracy	75.1 [72.2, 77.7]	68.4 [65.4, 71.3]	78.8 [76.1, 81.3]	84 [81.6, 86.2]
Sensitivity	43.8 [39.0, 48.8]	40.2 [35.5, 45.1]	53.8 [48.8, 58.6]	67.1 [62.3, 71.5]
Specificity	97.3 [95.5, 98.4]	88.5 [85.5, 90.9]	96.6 [94.6, 97.8]	96.0 [94.0, 97.4]
False negative	56.2 [51.2, 61.0]	59.8 [54.9, 64.5]	46.2 [41.4, 51.2]	32.9 [28.5, 37.7]
False positive	2.7 [1.6, 4.5]	11.5 [9.1, 14.5]	3.4 [2.2, 5.4]	4.0 [2.6, 6.0]
PPV	91.9 [86.9, 95.1]	71.2 [64.9, 76.9]	91.7 [87.3, 94.8]	92.3 [88.6, 95.0]
NPV	70.9 [67.6, 74.0]	67.6 [64.1, 70.9]	74.6 [71.3, 77.7]	80.4 [77.2, 83.3]

PPV = positive predictive value, NPV – negative predictive value

Maisel et al (2010) conducted a subgroup analysis on the same patient group to ascertain whether acoustic cardiography in combination with BNP testing would improve the diagnostic accuracy of heart failure in obese patients, patients with intermediate BNP values and patients with renal dysfunction. As stated above, of the 995 enrolled patients, 413 (42%) had a final diagnosis of HF. Upon patient

presentation at emergency, median BNP values were 823 and 51.5 pg/ml for those with and without HF, respectively. Although the correlation of BNP values with the strength of S3 was significantly greater ($p = 0.002$) in patients with HF ($r = 0.33$) than in those without HF ($r = 0.17$), the correlation was weak. The median strength of S3 and BNP levels in patients with HF ($n=139$) were 4.7 and 1003 pg/ml, respectively compared to S3 and BNP levels of 3.1 and 69 pg/ml for patients without HF ($n=57$).

The use of S3 acoustic cardiography improved the diagnostic accuracy for those patients ($n=208$) with an intermediate BNP level (100-499 pg/ml) from 46.8 to 68.6 per cent. The detection of a S3 heart sound in these patients significantly predicted 90-day adverse events with an odds ratio of 2.5 (95% CI [1.3, 4.9], $p=0.008$). However, the detection of a S3 heart sound in patients with BNP levels <100 pg/ml or >500 pg/ml was not significant on predicting adverse events at 90-days with odds ratios of 1.7 and 1.6, respectively.

Patients were classified into three subgroups according to their body mass index (BMI). Those with a BMI of <25 , 25-30 and >30 were classified as lean or normal ($n=245$), overweight ($n=221$) and obese ($n=332$), respectively. The specificity of acoustic cardiography remained high for all patients regardless of BMI, however the sensitivity decreased markedly for obese patients, despite the strength of the S3 remaining constant across all three sub-groups. Acoustic cardiography performed better than physician auscultation regardless of BMI (Table 2).

Table 2 BMI subgroup analysis: sensitivity and specificity of acoustic cardiography and auscultation

	BMI <25	BMI 25-30	BMI >30
Acoustic cardiography			
Sensitivity	69%	44%	28%
Specificity	73%	90%	88%
Physician auscultation			
Sensitivity	41%	17%	14%
Specificity	98%	95%	99%
Strength of S3	4.0 ± 2.0	4.0 ± 1.7	3.8 ± 1.7

In patients with moderate to severe kidney dysfunction (glomerular filtration rate <60 ml/min) the presence of a S3 heart sound was associated with a risk of 90-day adverse events.

These results indicate that S3 is a useful adjunct to BNP for the diagnosis of heart failure and is largely unaffected by the patient's body mass index (Maisel et al 2010).

An earlier study by Collins et al reported on the use of acoustic cardiography to predict elevated left ventricular (LV) filling pressure in patients admitted for elective right and left heart catheterisation using the bedside version of the AUDICOR device. An *elevated* LV filling pressure is the reference standard diagnosis for acute decompensated HF. Previous studies had indicated that LV systolic time, S3 score,

QTc interval³ and negative area of the P wave could be combined to estimate the probability of an elevated filling pressure, however the LV filling pressure was estimated using Doppler echocardiography. A more accurate measurement of LV filling pressure may be obtained during right heart catheterisation. A pulmonary capillary wedge pressure (PCWP) of >15 mm Hg is indicative of an elevated LV filling pressure (Collins et al 2010).

Although 68 adult patients (>18 years) were enrolled in the study, all baseline measurements were only obtained in 66 patients. Of these patients, 39 (59.1%) had an elevated PCWP \geq 15 mm Hg. Median S3 scores were significantly higher in those patients with an elevated PCWP (87 vs 28, $p=0.001$). Individuals with an elevated PCWP were more likely to have a history of hypertension ($n=22$, $p=0.002$) and pulmonary hypertension ($n=23$, $p<0.001$) compared to those with a PCWP of <15mm Hg. The ejection fraction did not differ between the two groups ($p=0.54$) but diastolic blood pressure ($p=0.007$), right atrial pressure ($p<0.001$) and pulmonary artery systolic pressure ($p<0.001$) were higher in those patients with an elevated PCWP. Using the validated model the estimated probability of an elevated PCWP resulted in an area under the curve of 0.76 (95% CI [0.64, 0.88]). These results indicate that the presence of a S3 heart sound may be a surrogate measure for the presence of elevated LV filling, and by extension the presence of HF (level III-2 prognostic evidence).

COST IMPACT

In 2003, Peacock et al (2006) conducted a cost analysis of patients presenting to an emergency department with symptoms of acute decompensated heart failure (ADHF) including dyspnoea, fatigue and extremity oedema. A total of 340 patients satisfied the inclusion criteria (median age 61 years, range 20-97 years), with 48 per cent of these patients having a previous diagnosis of HF. The ejection fraction (EF) was abnormal in 31 per cent of the 100 patients in whom it was measured ($EF<40\%$). BNP levels were determined in 250 patients and all patients underwent S3 detection using the AUDICOR device. Two cardiologists blinded to the results of the S3 detection determined whether ADHF was present or not based on other clinical data. The overall misdiagnosis rate was 14 per cent, with 43/47 patients misdiagnosed for ADHF when it was present. Using the AUDICOR alone in these 43 patients would have identified an additional 15 (34.9%) patients with ADHF (false negatives). Two of these patients were sent home, 12 were admitted to a non-ICU setting and one was admitted to ICU. However of the 206 patients correctly identified as *not* having HF, 14 (6.8%) would have been identified as having HF based on AUDICOR results alone (false positives). Ten of these patients were discharged home and four were admitted to a non-ICU setting. The specificity for S3 alone was 93.3 per cent with a 95% CI

³ QTc interval = the QT *interval* corrected for heart rate. The QT interval generally represents electrical depolarisation and repolarisation of the left and right ventricles.

[89.1, 96.0]. Specificity increased when S3 was used in conjunction with BNP. For patients with an intermediate BNP value (100-500 pg/ml) the specificity was 97.6 (95% CI [93.2, 99.2]) and for patients with BNP values >500 pg/ml specificity was 100 per cent (95% CI [97.0, 100]). The median hospital charges for patients correctly diagnosed in the emergency department as having HF was US\$7,977 (n=88) compared to US\$10,508 for patients with HF who were misdiagnosed with HF in the emergency department. The difference between the two values of \$2,500 represents a 32 per cent increase in costs (Peacock et al 2006b). As this study was conducted in the United States, these costs may not extrapolate to the Australasian health system.

The AUDICOR device is currently being marketed at an initial capital cost between US\$10-20,000, depending on whether the TS or 200 model is purchased. Consumables, including the chest sensors, for each diagnosis cost approximately US\$50 (personal communication Inovise Medical, Inc).

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

No issues were identified/raised in the sources examined.

OTHER ISSUES

No issues were identified/raised in the sources examined.

SUMMARY OF FINDINGS

The studies included in this assessment were all published by the same research group. The studies indicated that the presence of a S3 heart sound may correlate with symptoms of heart failure, especially when used in conjunction with other diagnostic measures such as BNP, to *rule out* the presence of heart failure. S3 may be particularly useful in patients with intermediate BNP levels or obese patients. The non-invasive measurement of S3 may be cost-saving, however a cost-effectiveness analysis is required. Further randomised controlled trials including a health economics analysis would be beneficial.

HEALTHPACT ASSESSMENT:

Although the good level of comparative evidence indicated that the adjunctive use of acoustic cardiography may be of benefit in the diagnosis of heart failure, the application of this technology in the acute setting was considered impractical. Therefore HealthPACT does not intend to further review this technology

NUMBER OF INCLUDED STUDIES

Total number of studies	3
Level III-2 prognostic evidence	3

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SEARCH CRITERIA TO BE USED:

Dyspnea/etiology

Electrocardiography/instrumentation/*methods

Heart Auscultation

Heart Failure/complications/*diagnosis

Heart Sounds