Australian Government

Department of Health and Ageing

Australia and New Zealand Horizon Scanning Network

ANZHSN

AN INITIATIVE OF THE NATIONAL, STATE AND TERRITORY GOVERNMENTS OF AUSTRALIA AND THE GOVERNMENT OF NEW ZEALAND

National Horizon Scanning Unit
Horizon scanning prioritising summary

Update Number 6

USCOM cardiac output monitor for patients requiring haemodynamic monitoring

June 2006

AHTA

Adelaide Health Technology Assessment

[add ISSN]
[add Publications Approval Number]

Electronic copies can be obtained from http://www.horizonscanning.gov.au

Enquiries about the content of this summary should be directed to:

HealthPACT Secretariat
Department of Health and Ageing
MDP 106
GPO Box 9848
Canberra ACT 2606
AUSTRALIA

The production of this *Horizon scanning prioritising summary* was overseen by the Health Policy Advisory Committee on Technology (HealthPACT), a sub-committee of the Medical Services Advisory Committee (MSAC). HealthPACT comprises representatives from health departments in all states and territories, the Australia and New Zealand governments; MSAC and ASERNIP-S. The Australian Health Ministers' Advisory Council (AHMAC) supports HealthPACT through funding.

This *Horizon scanning prioritising summary* was prepared by Elizabeth Buckley, Linda Mundy and Janet Hiller from the National Horizon Scanning Unit, Adelaide Health Technology Assessment, Discipline of Public Health, Mail Drop 511, University of Adelaide, South Australia, 5005.

UPDATE PRIORITISING SUMMARY

REGISTER ID: **000168**

NAME OF TECHNOLOGY: **USCOM CARDIAC OUTPUT MONITOR**

PURPOSE AND TARGET GROUP: **ULTRASONIC CARDIAC OUTPUT MEASUREMENT IN PATIENTS REQUIRING HAEMODYNAMIC MONITORING**

STAGE OF DEVELOPMENT (IN AUSTRALIA):

☐	Yet to emerge	☐	Established
☐	Experimental	☐	Established *but* changed indication or modification of technique
☐	Investigational	☐	Should be taken out of use
☒	Nearly established		

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

☒	Yes	ARTG number	81047
☐	No		
☐	Not applicable		

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
Australia		✓	
Germany	✓		
Italy	✓		
India	✓		

IMPACT SUMMARY:

USCOM, an Australian company, provides the USCOM cardiac output monitor with the aim of diagnosing cardiac output in patients requiring haemodynamic monitoring. The USCOM monitor was approved by the Therapeutic Goods Administration (TGA) in November 2001 and was recently approved in the United States (February 2005).

BACKGROUND

Cardiac output is defined as the total volume of blood ejected by the heart ventricle per minute and is calculated as the product of the heart's stroke volume and the heart rate, expressed as ml/min or L/min. The normal range for people in the resting state is 4 to 8L/min (Beers and Berkow 1999).

Cardiac output is a fundamental measure of the adequacy of myocardial function to meet the perfusion needs of tissue at any time. Decreases in cardiac output over time (when cardiac output is measured under similar conditions) may signal myocardial functional deterioration and the onset or progression of heart failure. On the other hand, improved cardiac output

observed over a period of time may indicate a positive response to medical therapy (Demaria and Raisinghani, 2000).

The USCOM is a portable Continuous Wave Doppler device, which uses an ultrasonic transducer to measure blood flow transcutaneously. The transducer is placed over the patient's pulmonary or aortic valves to measure the stroke volume and cardiac output. Changes in blood flow patterns may indicate changes in cardiac function and continuous monitoring may be used for the early detection of disease. The USCOM allows beat-to-beat quantitative evaluation of cardiac haemodynamics and can be used to confirm normal cardiac function, detect and quantify abnormal function, and to evaluate the effectiveness of cardiovascular therapies (United States Food and Drug Administration 2005).

CLINICAL NEED AND BURDEN OF DISEASE

Monitoring cardiac output for both adult and paediatric patient groups is important in many medical situations where haemodynamic assessment is required, particularly during anaesthesia and in acute and coronary care situations.

A number of Medicare Benefits Schedule (MBS) item numbers relate to cardiac output measurements (13818, 22015, 38200, 38203, 38206). The Health Insurance Commission reported that a total of 7,074 procedures were performed under these MBS item numbers in a private hospital setting during the period from July 2003 to July 2004.

DIFFUSION

The USCOM was first installed in seven hospitals across Australia in 2003 for clinical use and assessment in a variety of specialist medical disciplines, including paediatrics, anaesthetics, cardiology and intensive care (USCOM 2005). To date, USCOM has sold approximately 50 devices in Australia, Europe and Asia (personal communication, USCOM general manager, April 01, 2005).

It is likely that this device would receive rapid uptake in emergency medicine, intensive care and rural and remote areas as it is portable and may overcome the limitations of more invasive techniques.

COMPARATORS

There are several invasive and non-invasive methods for measuring cardiac output. The gold standard in measuring cardiac output is thermodilution. The thermodilution technique uses a special thermistor-tipped catheter (Swan-Ganz) which is inserted from a peripheral vein into the pulmonary artery. Cold saline of a known temperature and volume is injected into the right atrium from a proximal catheter port. The saline mixes with the blood as it passes through the ventricle and into the pulmonary artery, cooling the blood. The blood temperature is measured at the catheter tip lying within the pulmonary artery and a computer is used to acquire the thermodilution profile and compute the flow (Klabunde 2005). This technique takes repeated measures of mean cardiac output. Measuring cardiac output by thermodilution is rapid, although it can be expensive and may have risks associated with insertion or removal and maintenance of the catheter (Cholley 1998).

An alternative invasive catheterisation method is the Fick oxygen technique (Gola et al, 1996) Cardiac output is obtained by measuring the rate of oxygen consumption by the lungs, divided by the difference in oxygen content of arterial blood and mixed venous blood. Disadvantages of this technique include the need for right-sided heart catheterisation and obtaining expired gas measurements, which are invasive and complicated and in addition cannot give instantaneous results (Cholley 1998).

Another means to estimate cardiac output is the transesophageal echocardiographic approach. By visualising the heart blood flow velocity directly, the echocardiographic approach overcomes several limitations of the above methods, but is strongly operator-dependent and may not always be readily available. Heavy sedation or anaesthesia of the patient is necessary and the equipment required to perform this technique is expensive (Demaria and Raisinghani, 2000).

There are several non-invasive cardiac output devices currently available. One uses the reverse Fick principle utilising expired oxygen. The patient re-breathes into a measuring system through a mask and the concentration of oxygen is calculated. Changes in electrical impedence in the thorax is measured by a bioimpedance device and used to calculate fluid volumes (personal communication, cardiologist, April 01, 2005).

EFFECTIVENESS AND SAFETY ISSUES

The USCOM was compared to the thermodilution technique (level III-1 diagnostic evidence) in a group of intensive care patients (n=22), after cardiac surgery (Tan et al 2005). All patients received both standard thermodilution cardiac output measurement using a pulmonary artery catheter as well as USCOM measurements of cardiac output. Three to five thermodilution readings were recorded for all patients and the mean value was recorded as the $CO_{PAC.}$ USCOM measurements were performed by a single operator who was blinded to the CO_{PAC} readings. Forty sets of paired measurements were obtained. Some variation in the pulmonary flow profiles were recorded from the second to the fourth intercostal spaces (second intercostal space, n=11; third intercostal space n=25; fourth intercostal space; n=4).

Tan et al (2005) reported no adverse events or complications with the use of the USCOM device during this study. Comparison of the two techniques showed a mean difference in cardiac output measurements of ±0.82 L/min (95% CI -0.09, 0.44) and the limits of agreement (Bland-Altman) were -1.43 (-1.88 to -0.98) and 1.78 (1.33 to 2.23).

O'Driscoll et al (2005) presented preliminary results of a similar study at the 2nd Asian Pacific Congress of Heart Failure (APCHF), Singapore (unpublished, level III-2 diagnostic evidence). Cardiac output was measured in 15 patients with both the USCOM and a thermodilution catheter. A correlation of $r^2 = 71.4\%$ was obtained between the diagnostic techniques, and the Bland Altman analysis of cardiac outputs of < 5L/min had a bias of 0.12 and limits of agreement of -1.21 – 1.45 L/min. (O'Driscoll et al 2005). The USCOM tended to underestimate cardiac output when it was greater than 5L/min, when compared to thermodilution.

There are several abstracts of unpublished studies with similar levels of evidence of the USCOM listed on the company website in different clinical situations, including emergency departments, air rescue, intensive care and patients undergoing right heart catheterisation (USCOM 2005). There have been approximately 20 conference/meeting presentations on the validation of the USCOM. Five of these studies directly compared the USCOM to thermodilution using Swan Ganz catheters (personal communication, USCOM general manager, April 01, 2005). To date, in addition to the study by Tan et al (2005) there has been only one other published, peer-reviewed paper which described a study conducted on dogs.

COST IMPACT

The manufacturer claims that the use of the USCOM would result in cost saving, as it is not as expensive to use as the invasive cardiac output monitoring methods. It is reasonable to expect a reduction in the costs associated with surgical catheterisation, anaesthesia and personnel time. It is also claimed that the USCOM is more cost-effective when compared to other non-invasive methods. However, at the time of writing this summary there are no

published studies that examine the cost impact of the USCOM compared to any of the current methods available for determining cardiac output.

The cost of the USCOM is A$42,000. The current fee for the MBS item numbers for measuring cardiac output range from $96.50 (item number 13818) to $545.25 (item number 38206).

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

No issues were identified/raised in the sources examined.

OTHER ISSUES

The chairman of USCOM co-authored several of the abstracts presented on the company website.

APRIL 2005 - CONCLUSION:

The use of USCOM as a rapid, non-invasive diagnosis and monitoring tool may have application in the measurement of cardiac output in patient groups or situations where the gold standard is difficult to perform. Although the USCOM appears to have diffused into several Australian hospitals, there are insufficient empirical data on its impact. There are few published studies available to demonstrate the accuracy of the device and safety compared to other methods. Therefore, it was recommended that this technology be monitored.

APRIL 2005 - SOURCES OF FURTHER INFORMATION:

Beers, M.H., Berwkow, R. (1999) The Merck Manual of Diagnosis and Therapy. Merck Research Laboratories.

Bein, B., Worthmann, F. et al (2004). 'Comparison of esophageal Doppler, pulse contour analysis, and real-time pulmonary artery thermodilution for the continuous measurement of cardiac output', *J Cardiothorac Vasc Anesth,* 18 (2), 185-189.

Cholley, B.P. (1998) 'Benefits, risks and alternatives of pulmonary artery catheterization' *Curr Opin Anaesthesiol,* 11(6), 645-650

De Maria, A. N. & Raisinghani, A. (2000). 'Comparative overview of cardiac output measurement methods: has impedance cardiography come of age?' *Congest Heart Fail,* 6 (2), 60-73.

Engoren, M. & Barbee, D. (2005). 'Comparison of cardiac output determined by bioimpedance, thermodilution, and the Fick method', *Am J Crit Care,* 14 (1), 40-45.

Gola, A., Pozzoli, M. et al (1996). 'Comparison of Doppler echocardiography with thermodilution for assessing cardiac output in advanced congestive heart failure', *Am J Cardiol,* 78 (6), 708-712.

Katz, W. E., Gasior, T. A. et al (1993). 'Transgastric continuous-wave Doppler to determine cardiac output', *Am J Cardiol,* 71 (10), 853-857.

Klabunde, R. E. (2005). *Cardiovascular Physiology Concepts* [Internet] Available from: http://www.cvphysiology.com/textbook.htm [Accessed April 13, 2005]

Looyenga, D. S., Liebson, P. R. et al (1989). 'Determination of cardiac output in critically ill patients by dual beam Doppler echocardiography', *J Am Coll Cardiol,* 13 (2), 340-347.

Moxon, D., Pinder, M. et al (2003). 'Clinical evaluation of the HemoSonic monitor in cardiac surgical patients in the ICU', *Anaesth Intensive Care,* 31 (4), 408-411.

Nishimura, R. A., Callahan, M. J. et al (1984). 'Noninvasive measurement of cardiac output by continuous-wave Doppler echocardiography: initial experience and review of the literature', *Mayo Clin Proc,* 59 (7), 484-489.

O'Driscoll, G., Wright, J.J., Wright, I.W., Green, D.J., Phillips, R.A., (2005.) "Cardiac Output Measurement with the USCOM Ultrasonic Cardiac Output Monitor"

Abstract presented at the 2nd Asian Pacific Congress of Heart Failure (APCHF), Singapore, January 12, 2005

Royse, C. F., Royse, A. G. et al (1999). 'Measurement of cardiac output by transoesophageal echocardiography: a comparison of two Doppler methods with thermodilution', *Anaesth Intensive Care*, 27 (6), 586-590.

Tan, H. L., Pinder, M. et al (2005). 'Clinical evaluation of USCOM ultrasonic cardiac output monitor in cardiac surgical patients in intensive care unit', *Br J Anaesth*, 94 (3), 287-291.

United States Food and Drug Administration (2005) *K043139 510 (K) Summary*[Internet] Available from:http://www.fda.gov/cdrh/pdf4/K043139.pdf (Accessed March 30, 2005).

USCOM (2005). *USCOM NEWS* [Internet] Available from: http://www.uscom.com.au/USCOM%20news/news12_05_03.htm , (Accessed March 30, 2005).

Vandenbogaerde, J. F., Scheldewaert, R. G. et al (1986). 'Comparison between ultrasonic and thermodilution cardiac output measurements in intensive care patients', *Crit Care Med*, 14 (4), 294-297.

SEARCH CRITERIA TO BE USED:

Cardiac Output
Cardiac Surgical Procedures
Heart Failure, Congestive/ diagnosis/ physiopathology/ultrasonography
Hemodynamic Processes
Intensive Care/ methods
Monitoring, Physiologic/instrumentation/methods
Thermodilution

JUNE 2006 UPDATE - EFFECTIVENESS AND SAFETY ISSUES

Knobloch et al. (2005a) conducted a study (level III-2 diagnostic evidence) which compared the measurement of cardiac output (CO) using the non-invasive Doppler technique (USCOM) to measurements obtained from an invasive thermodilution technique (Swan-Ganz pulmonary artery catheter, PAC) in postcardiac surgical patients (n=36). Measurement of CO was also simultaneously taken by PAC and USCOM in 6 patients intra-operatively.

The post-operative CO measurements for USCOM and PAC were 5.15 ± 1.98L/min (95% CI 4.86 – 5.44L/min) and 4.92 ± 2L/min (95%CI 4.63 – 5.22L/min) respectively. Bland-Altman analysis of the mean difference between the measures was -0.23 ± 1.01L/min. Correlation between the USCOM and PAC methods was determined to be significant at 0.794 ($p<0.01$) demonstrating that USCOM is an accurate tool for the measurement of CO (Knobloch et al. 2005a).

Intra-operatively (n=6) the measurement of CO was very similar between the two techniques. USCOM had a mean CO of 4.95 ± 1.02L/min compared to the PAC-measured mean CO of 4.97 ± 0.98L/min ($p>0.05$) (Knobloch et al. 2005a).

While these data indicate that there is a high correlation between USCOM and PAC, Knobloch et al. (2005a) acknowledged that their study had a number of limitations. Firstly, the use of PAC thermodilution as the gold standard has been debated in the literature due to concerns regarding its accuracy. Secondly, USCOM measures CO beat-to-beat compared to PAC measured CO which is over a non-simultaneous hemodynamic time interval. The authors also acknowledge that the use of a single expert operator of the USCOM may result in these results not being reproducible by less experienced operators (Knobloch et al. 2005a).

Dey and Sprivulis (2005) developed a training package (independent of the manufacturer) for the use of USCOM. Four emergency physicians and one geriatrician underwent training using this package and skill acquisition was assessed at the 5^{th}, 10^{th}, 15^{th} and 20^{th} patient examination using six image-scoring criteria developed to assess the acoustic image quality (level IV diagnostic evidence). Each person was blinded to the image score and CO measurements of the other participants. The level of skill was measured by the average image quality score and intra-assessor difference in aortic and pulmonary cardiac index measurements. A protocol (The "Fremantle Protocol") was then developed to optimize interassessor reliability which was subsequently assessed. Two emergency physicians performed blinded measurement of CO using the protocol developed. Twenty patients were recruited for this study who presented with both injury and illness. Inclusion criteria were cognitive capacity sufficient to allow informed consent and an age greater than 17years.

After using the training package, the average image quality score (scored out of a possible six) improved between the 5^{th} and 20^{th} assessment from 4.6 (95% CI 4.0 – 5.3) to 5.5 (95% CI 5.0 – 6.0), p=0.02. The average difference between assessors also improved between the 5^{th} and 20^{th} assessment from 17% (95% CI 4 – 25) to 5% (95% CI 0 – 11), p=0.02 (Dey and Sprivulis, 2005).

Interassessor reliability showed a high correlation over 52 CO assessments in 21 patients, r=0.96 (95% CI 0.90 – 0.98), $p<0.001$. The average difference in CO and cardiac index between assessors was 0.2L/min (4%, 95% CI 3 – 6) and 0.1L/min/m² (4%, 95% CI 2 – 6) respectively (Dey and Sprivulis, 2005).

Knobloch et al. (2005b) (Level IV diagnostic evidence) evaluated non-invasive CO measurements using USCOM in preclinical emergency medicine in air rescue service. CO was determined using USCOM in 32 patients at the scene and during helicopter transport. Of these 32 patients, 19 were unconscious and 13 were conscious and 7 patients were hemodynamically stable. The average CO measured by USCOM was 4.8 ± 0.7L/min. The highest CO was measured in a patient with sepsis and during a grand-mal-status in epilepsy (CO 8.2L/min) (Knobloch et al. 2005b). The authors concluded that non-invasive beat-to-beat CO measurement is possible in an air rescue service setting.

JUNE 2006 – CONCLUSION:

Recently published data indicate that the USCOM shows accuracy and agreement with the reference standard thermodilution, although recent concerns have been raised regarding the accuracy of pulmonary artery catheterization with low cardiac output. The non-invasive nature of this technique suggests that it would be suitable for use in settings where procedural risk, time and equipment requirements are serious considerations.

JUNE 2006 - HEALTHPACT ACTION:

As the technology appears likely to enter the health system, a horizon scanning report is recommended.

JUNE 2006 - SOURCES OF FURTHER INFORMATION:

Dey, I. and Sprivulis, P. (2005). 'Emergency physicians can reliably assess emergency department patient cardiac output using the USCOM continuous wave Doppler cardiac output monitor.' *Emergency Medicine Australasia* 17(3), 193-9.

Knobloch, K., Hubrich, V., et al. (2005a). '[Non-invasive determination of cardiac output by continuous wave Doppler in air rescue service].' *Anasthesiol Intensivmed Notfallmed Schmerzther* 40(12), 750-5.

Knobloch, K., Lichtenberg, A., et al. (2005b). 'Non-invasive cardiac output determination by two-dimensional independent Doppler during and after cardiac surgery.' *Annals of Thoracic Surgery* 80(4), 1479-83.

LIST OF STUDIES INCLUDED

Total number of studies	
Level III-2 diagnostic evidence	1
Level IV diagnostic evidence	2