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PulseTrace: Non-invasive, rapid assessment of arterial stiffness to identify patients at risk of heart disease and stroke.

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PRIORITISING SUMMARY

REGISTER ID: **000128**

NAME OF TECHNOLOGY: **PULSETRACE**

PURPOSE AND TARGET GROUP: **NON-INVASIVE, RAPID ASSESSMENT OF ARTERIAL STIFFNESS TO IDENTIFY PATIENTS AT RISK OF HEART DISEASE AND STROKE**

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	63534
☐	No	☐	Not applicable

This technology is registered on the Australian Register of Therapeutic Goods and is available for use in public and private hospital cardiac clinics. PulseTrace is distributed in Australia by Tag Medical.

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
Australia	underway		
United Kingdom	✓		

IMPACT SUMMARY:

Micro Medical Ltd manufacture the PulseTrace device to non-invasively measure arterial stiffness using pulse wave velocity, with the aim of identifying patients at risk of heart attack and stroke.

BACKGROUND

The PulseTrace is a desktop instrument, which measures the Stiffness Index (SI), a measure of large artery stiffness and the Reflection Index (RI), a measure of the vascular tone of small arteries. A small finger probe, which picks up the pulse wave form, is attached to the patient's right index finger and records waveforms for 15-30 seconds (Figure 1). A digital volume pulse can be obtained by measuring the transmission of infrared light through the finger (photoplethysmography), with the amount of light proportional to the volume of blood in the finger.

Figure 1 Pulse Trace (Printed with permission Micro Medical Ltd)

The systolic component of the waveform occurs as the heart contracts and creates a direct wave from the aorta down the arm to the finger. The diastolic component is formed by the pressure wave being transmitted from the ventricle along the aorta to the small arteries in the lower body, where it is reflected back along the aorta to the finger (Figure 2). The diastolic peak is related to the amount of pressure wave reflection and the height of this peak, expressed as a percentage of the systolic peak, is the RI. The time delay (T) between the systolic and diastolic peaks is determined by the transit time from the root of the subclavian artery to the site of reflection and back to the subclavian artery. This distance is assumed to be proportional to the patient's height (h), the pulse wave velocity in the aorta and large arteries can therefore be used to provide a stiffness index (SI=h/T). The SI correlates with aortic pulse wave velocity (PWV) and is influenced by age and blood pressure (Micro Medical Ltd 2004a and 2004b).

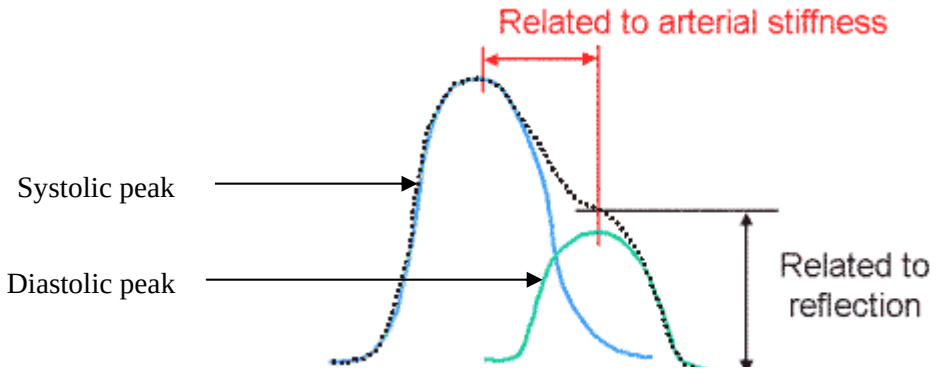

Figure 2 Digital volume pulse (Micro Medical Ltd 2004b).

PulseTrace may be contraindicated in patients with poor peripheral perfusion or Raynaud's syndrome. A poor signal may be produced in these patients; however, this may be overcome by conducting examinations in a warm room.

Endothelial dysfunction may be an initiating event in vascular disease. Pulse wave analysis can be used to assess endothelial function by measuring changes in pressure wave reflection in response to a vasodilator drug acting through the release of endothelium derived vasodilators. Vasoactive drugs act by reducing arterial tone, thereby affecting pressure wave reflection. (Micro Medical Ltd 2004a).

CLINICAL NEED AND BURDEN OF DISEASE

Heart failure as a principal diagnosis accounted for approximately 41,874 hospitalisations and 2,612 deaths in Australia during the period 2001-2002 (AIHW 2004). The number of public hospital separations for patients with congestive heart disease or left ventricular failure was 28,113 and 12,648 respectively in 2001-2002 (AIHW 2004). Prevalence of heart failure increases from 1% in 50-59 year-olds to 50% in people aged 85 years and older, and hospitalisation rates for heart failure are three times higher among people aged 75-84 years than in the 65-75 year group (AIHW 2003; Krum 2001). Based on overseas findings, it is predicted that 300,000 people have chronic heart failure in Australia (about 4% of the population over 45 years of age), and 30,000 new cases are diagnosed each year (Krum 2001). In addition there were 10,107 hospitalisations in Australia for stroke in the year 2001-02 (AIHW 2004).

DIFFUSION

The PulseTrace is currently in use in only a few hospitals and practices in Australia (personal communication Tag Medical). PulseTrace is being trialled at the (private) Ashford Hospital, South Australia and in the process of being validated by the University of South Australia, School of Health Sciences (personal communication Dr Jon Buckley, University of South Australia).

COMPARATORS

A patient is diagnosed with heart failure when three conditions are satisfied simultaneously. These include a clinical history or signs consistent with heart failure, such as dyspnoea and oedema, normal or near-normal systolic function, and evidence of abnormal diastolic relaxation. Establishing left ventricular diastolic dysfunction is the most definitive condition and is best determined by measuring the ratio of early to late or atrial ventricular filling velocity using echocardiography (NHF & CSANZ 2002).

EFFECTIVENESS AND SAFETY ISSUES

Several studies have demonstrated a correlation between aortic stiffness and coronary heart disease and stroke using previously validated measurements of pulse wave velocity (PWV) along the descending thoraco-abdominal aorta by the foot-to-foot velocity method (*ie not measured using the PulseTrace device*). The study by Laurent et al (2003) reported in 1715 hypertensive patients that PWV significantly predicted the occurrence of stroke death (level of evidence III-2). There was a relative increase in risk of 1.7 times (95%CI [1.5, 2.0], $p<0.0001$) for each standard deviation increase in PWV (4 metres/second). After adjustment for cardiovascular risk factors (age, cholesterol, diabetes, smoking, blood and pulse pressure), the predictive value of PWV remained significant (RR = 1.4, 95% CI [1.1, 1.7], $p=0.02$). Aortic stiffness as a predictor of all-cause (odds ratio for PWV 5m/s was 2.1, 95% CI [1.7, 2.7], $p<0.0001$) and cardiovascular mortality (odds ratio 2.4, 95% CI [1.8, 3.1], $p<0.0001$) was reported by Laurent et al (2001).

Millasseau et al (2002) conducted a study (level of evidence IV), which used PulseTrace to measure large artery stiffness derived from the digital volume pulse (SI_{DVP}), the timing of which depends on the PWV. The within-subjects reproducibility of the SI_{DVP} was assessed in eight healthy men by obtaining three measurements at weekly intervals. The coefficient of variation for SI_{DVP} was 9.6% (not significant). Eighty-seven normotensive individuals had their SI_{DVP} measured (8.4 m/s), which was similar to their determined PWV (9.3 m/s). In these individuals, SI_{DVP} had good correlation with age (r=0.7, $p<0.0001$), but poor-to-average correlation with systolic blood pressure (r=0.3, $p<0.01$), diastolic blood pressure (r= 0.48, $p<0.0001$), mean arterial pressure (r= 0.5, $p<0.0001$) and total cholesterol (r= 0.4, $p<0.01$). There was no correlation with pulse pressure.

Vasodilator agents (drugs or caffeine) affect the smooth muscle tone in small arteries. To assess whether the presence of vasodilator agents affects the interpretation of SI_{DVP} results a vasodilator drug was administered to nine normotensive males. Administration of glycerol trinitrate and placebo was randomised in a blinded manner over two days and the before and after effects were observed. The saline placebo had no effect on SI_{DVP}, heart rate or blood pressure. The effect of glycerol trinitrate on SI_{DVP} was modest, decreasing from 6.5 ± 0.19 m/s at baseline to 5.3 ± 0.27 m/s, $p<0.001$), supporting the concept that SI_{DVP} is influenced predominantly by the stiffness of the large elastic arteries (Millasseau et al 2002).

COST IMPACT

Tag Medical estimate the current a current Australian price of $12,500 for the PulseTrace device.

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

No issues were identified/raised in the sources examined.

CONCLUSION:

The association between pulse wave velocity and aortic stiffness as a predictor for risk of cardiovascular disease appears to be well established, however there is limited, poor quality evidence concerning the validation of the PulseTrace device to measure aortic stiffness.

HEALTHPACT ACTION:

Therefore, based on the potential clinical need and the ease of operation of the device, it is recommended that this technology be monitored.

SOURCES OF FURTHER INFORMATION:

AIHW (2003). *Heart failure...what of the future?,* Australian Institute of Health and Welfare, Canberra.

AIHW (2004). *AIHW National Hospital Morbidity Database* [Internet]. Australian Institute of Health and Welfare. Available from: http://www.aihw.gov.au [Accessed 28th September 2004].

Boutouyrie, P., Tropeano, A. I. et al (2002). 'Aortic stiffness is an independent predictor of primary coronary events in hypertensive patients: a longitudinal study', *Hypertension,* 39 (1), 10-15.

Cockcroft, J. R. & Wilkinson, I. B. (2002). 'Arterial stiffness and pulse contour analysis: an age old concept revisited', *Clin Sci (Lond),* 103 (4), 379-380.

Krum, H. (2001). 'Guidelines for management of patients with chronic heart failure in Australia', *Med J Aust,* 174 (9), 459-466.

Laurent, S., Boutouyrie, P. et al (2001). 'Aortic stiffness is an independent predictor of all-cause and cardiovascular mortality in hypertensive patients', *Hypertension,* 37 (5), 1236-1241.

Laurent, S., Katsahian, S. et al (2003). 'Aortic stiffness is an independent predictor of fatal stroke in essential hypertension', *Stroke,* 34 (5), 1203-1206.

Micro Medical Ltd (2004a). *Pulse Trace* [Internet]. Micro Medical Ltd. Available from: http://www.micromedical.co.uk/downloads/pdf/pulsetrace.pdf [Accessed 27th September 2004].

Micro Medical Ltd (2004b). *Pulse Trace* [Internet]. Micro Medical Ltd. Available from: http://www.micromedical.co.uk/pulsetrace.co.uk/pulseframes.htm [Accessed 27th September 2004].

Millasseau, S. C., Guigui, F. G. et al (2000). 'Noninvasive assessment of the digital volume pulse. Comparison with the peripheral pressure pulse', *Hypertension,* 36 (6), 952-956.

Millasseau, S. C., Kelly, R. P. et al (2002). 'Determination of age-related increases in large artery stiffness by digital pulse contour analysis', *Clin Sci (Lond)*, 103 (4), 371-377.

NHF & CSANZ (2002). *Guidelines on the Contemporary Management of the Patient with Chronic Heart Failure in Australia*, National Heart Foundation of Australia and Cardiac Society of Australia & New Zealand.

Woodman, R. J. & Watts, G. F. (2003). 'Measurement and application of arterial stiffness in clinical research: focus on new methodologies and diabetes mellitus', *Med Sci Monit*, 9 (5), RA81-89.

SEARCH CRITERIA TO BE USED:

Arteries
Blood Pressure
Elasticity
Photoplethysmography
Risk Factors
Vascular Resistance
Aorta
Carotid Arteries
Coronary Disease/mortality
Hypercholesterolemia
Hypertension
Pulsatile Flow
Blood Flow Velocity
Fingers/blood supply
Regional Blood Flow
Algorithms