Issue 2, April 2007

ANZHSN Bulletin

'New health technologies identified through the Australia and New Zealand Horizon Scanning Network (ANZHSN)'

In This Issue...

Australian Government
Department of Health and Ageing

HealthPACT and Euroscan

In the first edition a description of the Horizon Scanning Network within Australia and New Zealand was outlined. This included the network hosted by MSAC and the links to all jurisdictions, the work programme and the dissemination of information and the links with clinical services were covered.

HealthPACT also belongs to an international organisation known as EuroScan, the European Information Network on new and changing health technologies.

EuroScan membership includes several European countries and some non-European countries including:

- Australia
- Canada
- Israel
- United Kingdom
- France
- Denmark
- Switzerland
- Spain
- Norway
- Sweden
- Netherlands

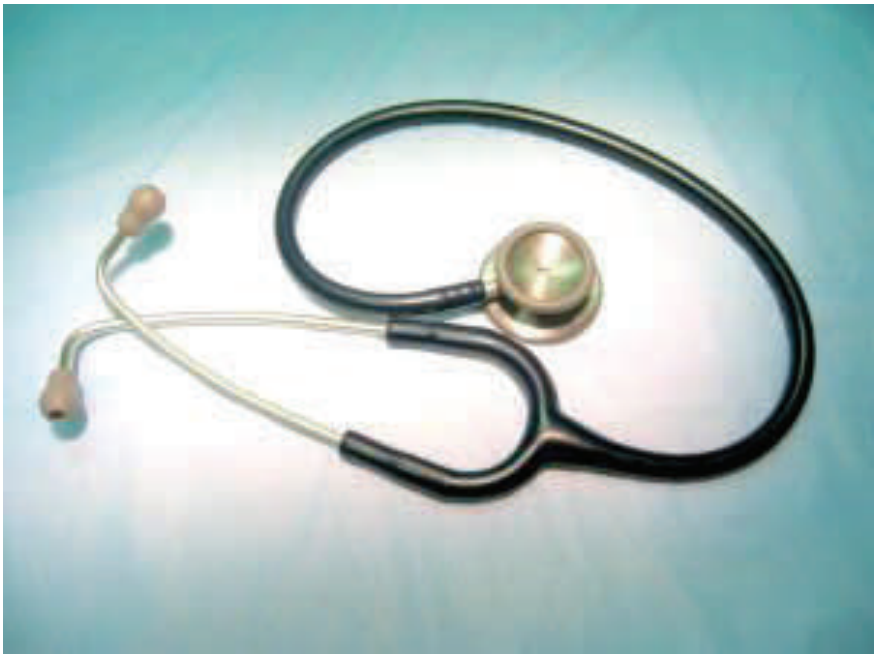
The EuroScan Secretariat is based in the University of Birmingham, United Kingdom. EuroScan maintains a database of all reports on emerging technologies prepared by member organisations and Australia is a major contributor to that database.

EuroScan has strong links with the European community, Health technology assessment agencies and also undertakes research into the diffusion of technologies.

EuroScan also assists in the techniques involved in the selection and prioritisation of new and emerging health technologies and through the member agencies has very strong and direct links to national health technology assessment bodies such as NICE in the United Kingdom, HAS in France and CADTH in Canada, and of course MSAC in Australia.

This collaboration and sharing of work is a very powerful and effective way of continuing to be active in covering the field of new and emerging health technologies.

Best Regards,
Professor Brendon Kearney
Chair of HealthPACT



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Genetic screening for Familial Hypercholesterolaemia: Dna detection of low density lipoprotein cholesterol receptor gene mutations in asymptomatic individuals for the diagnosis of FH

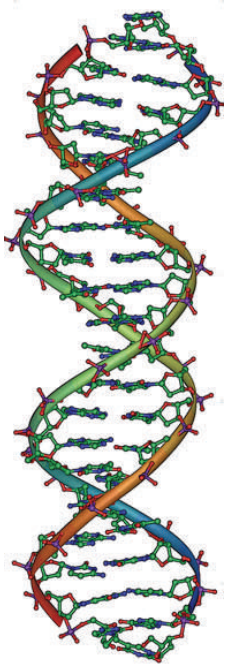
Familial hypercholesterolaemia (FH) is an inherited disorder of blood lipid metabolism that results in high levels of cholesterol (atherosclerosis). FH is characterised by one or more mutations in the LDL receptor (LDLR) gene, resulting in a deficiency of LDL receptors on the surface of blood cells, or an altered receptor structure that disrupts LDL uptake[1]. Individuals with FH have an increased risk of premature (<55 years in men and <65 years in women) cardiovascular disease and a reduced life expectancy. Approximately 85% of males and 50% of females with FH will suffer a coronary event before 65 years of age[2]. FH follows an autosomal dominant pattern of inheritance. In heterozygous familial hypercholesterolaemia, a defective LDL receptor has either zero or reduced LDL uptake capacity. This results in approximately twice the normal (7-10 mmol/L) levels of plasma LDL cholesterol. In homozygous FH there is almost no LDL receptor activity and LDL cholesterol levels are often extremely high >30mmol/L. There are an estimated 800 different mutations identified to date that can occur in the LDL gene that cause FH[2,3] and the array of mutations varies in different populations.

HOW IT WORKS

FH is rarely diagnosed before onset of premature CVD. A definitive diagnosis of FH can be achieved by the identification of known mutations. The genetic procedure developed for testing FH in Australia involves denaturing high-performance liquid chromatography (HPLC) and then confirming suspected mutations by DNA sequencing to detect mis-matches. HPLC is a method being adapted for the analysis of DNA fragments, by separating mixtures of DNA fragments based on size alone or based on size and sequence[4]. This method can be used for mutation screening of large genes. Some international laboratories use DNA sequencing alone.

THE EVIDENCE

Several studies report the detection rates of FH with genetic testing compared to clinical diagnosis[5,6,7]. In one of these studies, 408 patients were retrospectively categorised according to three different sets of clinical criteria and their distribution of patients was compared to the results of the genetic test. A mutation was found in 135/148 (33%) of the patients and only 71% of the mutation carriers fulfilled two out of three criteria for a clinical diagnosis of FH[5]. The largest study[6] found an LDLR mutation in 2400/4000 (52%) of patients who had previously been clinically defined with FH. This testing procedure involved identifying the 14 most prevalent Dutch LDLR gene mutations. This study examined



Right: The structure of part of a DNA double helix

Source: Wikipedia (http://en.wikipedia.org/wiki/Image:DNA_Overview.png)

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whether patients with a genetic diagnosis differed significantly from clinically diagnosed patients. The authors report that LDL cholesterol levels were higher in patients diagnosed genetically and that triglycerides levels were higher in patients without a genetic mutation[5]. The potential value of a genetic screening program depends on the prevalence of identified mutations in a population. The literature suggests that genetic testing should be limited to populations in which only a few mutations account for most FH cases, populations in which most causative mutations are known and in individuals with an uncertain clinical diagnosis with family members with known FH[2].

FUTURE STEPS

It is likely that a family cascade screening program in Australia would increase public costs of drug therapy due to greater detection of FH. However, successful treatment regimes have demonstrated cost-effectiveness and may have the potential to reduce the risk of CVD in patients who are currently asymptomatic. Given the potential positive therapeutic benefits of identifying family members of familial hypercholesteraemia probands, HealthPACT recommended a more detailed examination be conducted on this technology.

Written by Adrianna Parella, AHTA

The provision of free nicotine patches within smoking cessation programmes: Executive Summary

All forms of nicotine replacement therapy (NRT) can help people quit smoking, almost doubling long-term success rates and nicotine patches appear to be a well tolerated aid for some groups of smokers wishing to quit. It has been suggested that removing financial barriers to access may further increase the uptake of this quitting aid. This report summarises the evidence for the provision of free nicotine patches within smoking cessation programmes.

A total of 11 studies that have used control groups and randomisation were found but not all of these were directly relevant when examined more closely. A further 12 pseudo randomised controlled trials or comparative studies were also profiled and many of these studies directly compared free NRT with usual care. Only a small number of studies (n=2) were identified that considered issues of cost effectiveness for free NRT.

Overall, despite the number of studies, the evidence on provision of free nicotine patches within smoking cessation programmes from randomised controlled trials is equivocal. While NRT provided free is more effective than placebo, it is not clear whether the observed effect is over and above what it would be if the NRT was provided at cost to the user. Only one trial has directly compared a group receiving a free supply of patches to a group receiving a prescription and study design and response rate issues limited the conclusions that could be made. At present there is insufficient evidence to determine whether providing patches free is any more effective than providing potential quitters with a prescription, subsidy or voucher to purchase patches at a reduced price. Future provision of free NRT should preferably be piloted within the context of a randomised controlled trial so that data on its effectiveness relative to subsidised or full cost patches can be obtained.

Written By Carolyn Doughty, NZHTA

Source: stock.xchng (http://www.sxc.hu/photo/233164)

Nanomedicine: an Emerging Technology Bulletin: Executive Summary

A nanometre is 10^{-9} of a metre. To put nanotechnology into perspective, a human red blood cell is 8,000 nm in diameter and a human hair is approximately 70-80,000 nm thick. Nano-sized materials have a relatively large surface area and different optical, electrical and magnetic properties, which cause them to behave differently when compared to micro- or macro-sized particles of the same material. These properties can be exploited in the development of products that are capable of behaving quite differently to conventional medicines, medical devices and diagnostic techniques and will hopefully lead to cheaper, more efficient and more accurate health care products.

Nanotechnology or nanomedicine conjures up images of minute nanobots, injected into the bloodstream or implanted into the human body, acting as an all-seeing, all-doing surveillance, monitoring and diagnostic machine. Unfortunately nanobots are the stuff of science fiction and are unlikely to become a reality within the next twenty years. However, nanomedicine *is* a rapidly evolving field with some applications currently in commercial use and many more in the clinical or pre-clinical stage of development. The number of peer reviewed publications in nanomedicine is growing yearly and currently represents five per cent of all published nanotechnology papers. The strict regulation requirements of nanomedicine may mean that the introduction of nanomedicines may lag behind the introduction of other nanotechnologies like those in the engineering or structural materials field.

The structure of this Emerging Technology Bulletin follows the nanomedicine taxonomy development by the National Research Council of Canada and considered:

Biopharmaceutics;

Implantable materials;

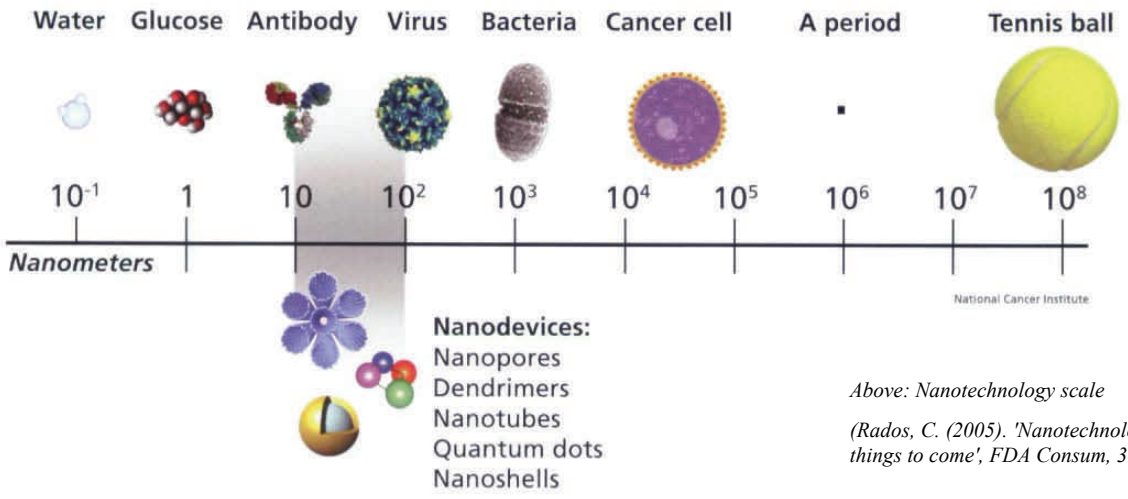
Implantable devices;

Surgical aids; and

Diagnostic tools.

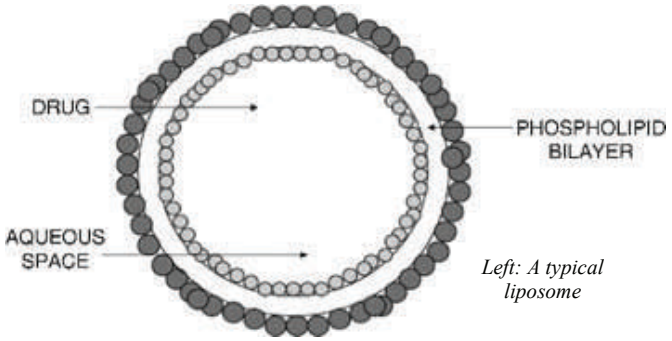
The one area expected to produce immediate results is that of drug delivery and drug discovery. New nano-formulations of existing toxic or harmful drugs are likely to be products that gain regulatory approval for use in humans in the immediate future. There are currently at least three marketed drugs that utilise nano-size liposomes; the anti-fungal agent amphotericin B and two chemotherapy agents, daunorubicin and doxorubicin. Abraxane, an albumin nanoparticle preparation of paclitaxel, is now in Phase II clinical trials. Although gene delivery is viewed as an extension of the drug delivery concept, it is unlikely that gene delivery will be in clinical use before five years as this research is at the pre-clinical stage, with *in vitro* and animal experiments currently being conducted.

Applications of nanotechnology applied to the coatings of implanted medical devices have the potential to reduce the incidence of infection (coatings of catheters with antimicrobial nanoparticles) and to improve their strength and osteoinductive ability (hip and knee replacements). Both of these applications have the potential to save the health system money by the prevention of nosocomial infection and the reduction in the number of replacement hip and knee operations performed. It is likely that the introduction of these



Above: Nanotechnology scale

(Rados, C. (2005). 'Nanotechnology: the size of things to come', FDA Consum, 39 (6), 40-42.)



Left: A typical liposome

(Sharma, G., Anabousi, S. et al (2006). 'Liposomes as targeted drug delivery systems in the treatment of breast cancer', J Drug Target, 14 (5), 301-310.)

technologies will be in the short term. Surgical tools, such as needles and scalpel blades, constructed with nanotechnology techniques are a reality. However, applications such as tissue regeneration utilising nanotechnology techniques is still at the *in vitro* or animal model experimental stage.

The field of diagnostics offers a huge potential for the uptake of nanotechnology. Imaging with quantum dots and lipid-based nanoparticles is still in the developmental, *in vitro* stage. However, one magnetic nanoparticle product, Combidex®, for imaging, has gained conditional FDA approval. Laboratory based diagnostic applications of nanotechnology are rapidly evolving and it is hoped that nanodiagnostics will result in improved sensitivity, and more rapid detection rates when compared to conventional diagnostic techniques. DNA microarrays are now being replaced by the development of nanoarrays, which are capable of exponentially higher levels of sample throughput.

There is limited information currently available on the potential risks that nanotechnology poses to human health and safety, or the direct risk of environmental contamination. The use of nanotechnology is likely to increase exponentially and therefore steps should be taken to address this lack of I nformation. Evaluation of the fate of nanoparticles, their adsorption, distribution, metabolism and excretion in the body, is required. Preliminary studies have demonstrated that for certain nanoparticles (TiO_2:P25), inhalation at low concentrations will cause inflammation and granulomas, however there are no studies to date that have documented the effects of long term exposure, and therefore higher accumulated doses, of nanoparticles.

The ethical considerations of nanomedicine are similar to those that should be considered when introducing *any* new technology. A great deal of discussion in respect to the ethical and social issues of nanomedicine/ nanotechnology has already taken place, despite the inability to predict or foresee what these implications may be.

In conclusion, nanomedicine is a rapidly evolving, complex area which may afford tremendous improvements in all aspects of medicine.

Written by Linda Mundy, AHTA

First level of hierarchy	Second level of hierarchy	Example of second level hierarchy
Biopharmaceutics	Drug Delivery	Drug encapsulation Functional drug carriers
	Drug discovery	
Implantable materials	Tissue repair and replacement	Implant coatings Tissue regeneration scaffolds
	Structural implant materials	Bone repair Bioresorbable materials Smart materials
Implantable devices	Assessment and treatment devices	Implantable sensors Implantable medical devices
	Sensory aids	Retina implants Cochlear implants
Surgical aids	Operating tools	Smart instruments Surgical robots
Diagnostic tools	Genetic testing	Ultra-sensitive labelling and detection technologies High throughput arrays and multiple analyses
	Imaging	Nanoparticle labels Imaging devices

Left: Nanomedicine hierarchy

Wolbring, G. (2003). The Triangle of Enhancement Medicine, Disabled People, and the concept of health: a new challenge for HTA, health research, and health policy, Alberta Heritage Foundation for Medical Research, Edmonton, Canada, www.ahfmr.ab.ca/download.php/954da463c9a6c633bdafefd1aaf23844.

Laparoscopic sleeve gastrectomy for the treatment of morbidly obese patients

Obesity is a condition in which sufferers have excessive fat deposits to a point where the person's health is at risk, eventually leading to mortality. Obesity is measured through the Body Mass Index (BMI) with people considered to be overweight at a BMI ≥ 25 and obese at a BMI ≥ 30[1]. Long-term studies have shown that conservative medical treatments are ineffective in patients with morbid obesity, with relapse rates of up to 90% irrespective of the choice of conservative treatment[2]. As a result of this, surgical treatments (bariatric surgery) have been increasingly utilised as a means of achieving weight loss in these patients. One of the latest surgical procedures currently being utilised is sleeve gastrectomy (also known as the gastric sleeve procedure or laparoscopic tube gastrectomy).

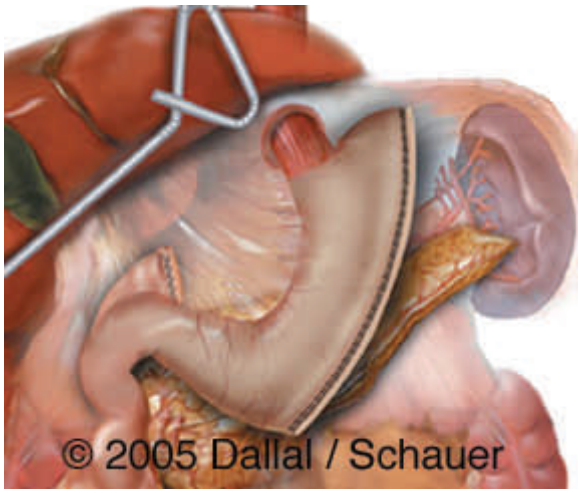
HOW IT WORKS

Laparoscopic sleeve gastrectomy (LSG) involves the surgical removal of the left side of the stomach resulting in a stomach which is approximately the size and shape of a banana[3] and does not require re-routing of intestines or implantation of an artificial device in the abdomen. Weight loss is achieved by the reduction in stomach size; and satiety is induced faster with less food. LSG has also been utilised as the first treatment step in super-obese patients or patients with high operative risk prior to performing more complicated procedures such as laparoscopic Roux-en-Y gastric bypass (LRYGBP).

THE EVIDENCE

The outcomes of 126 patients undergoing LSG as the first stage of two-stage treatment were evaluated (second treatment laparoscopic Roux-en-Y gastric bypass). Significant co-morbid conditions were present pre-operatively in most patients including sleep apnoea, hypertension and depression. The mean operative time was 143 ± 28 minutes with a mean hospital stay of 3 ± 1.7 days. Peri-operatively there were no deaths reported, however there was one late death in a woman who received conversion to open sleeve gastrectomy with previous abdominal injuries. The patient developed pulmonary embolus three months after surgery and did not recover. Eighteen post-operative complications were reported including 5 strictures, 2 leaks, 2 pulmonary embolisms, 5 patient requirements for > 24 hour ventilator support and 4 patients who developed renal insufficiency without the need for dialysis. Only 46% of patients were available for the 12 month follow-up. These patients had a mean excess weight loss of 45 ± 17%. A total of 36 patients went on to stage II with a mean interval of 12 ± 5 months. Patients who underwent the second stage experienced a decrease in BMI to 49.5 ± 8 with a mean weight loss of 43.6 kg (mean follow-up 7.1 ± 5 months). At 12 months, patients achieved an overall weight loss from 177 kg to 131 kg ($p = 0.05$) and BMI was significantly reduced from 65 ± 9 to 49 ± 8 ($p < 0.05$). In addition to this, the number of co-morbidities 12 months post-LSG decreased from 9 ± 3 to 6 ± 3. The authors feel that LSG does not sufficiently address medical problems associated with morbid obesity and recommend patients be evaluated for second stage gastric bypass to ensure long term weight loss.

A total of eight studies were included for assessment in this summary.



"Laparoscopic sleeve gastrectomy (LSG) involves the removal of the left side of the stomach"
(Source: American Society of Bariatric Surgery (ASBS))

FUTURE STEPS

The studies assessed in this summary indicate that LSG is capable of inducing substantial weight loss in patients and

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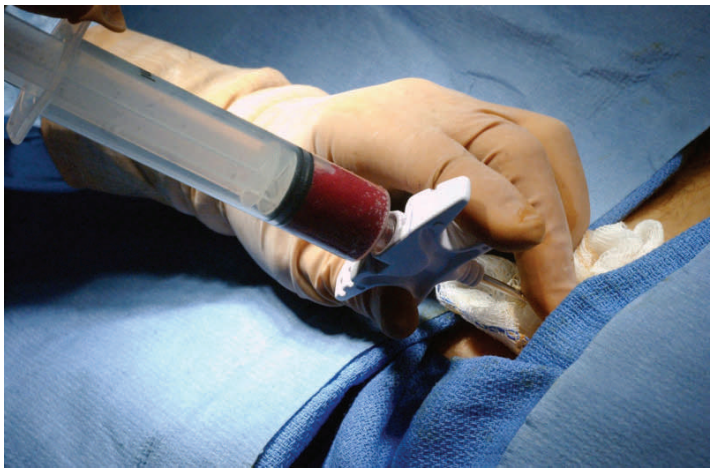
may be suitable as the ideal first stage operation in patients with BMI > 55[5]. A total of 3 studies reported deaths (one death each)[4,5,6] that were related to the procedure, severe complications (intra-abdominal bleeding/leakage, extraluminal bleeding) documented within these studies often required re-operation as well. The historical controlled study with the intragastric balloon suggests that LSG is capable of faster and greater weight loss[7], however the lack of concurrent controlled studies with appropriate comparators (e.g. laparoscopic gastric banding, stomach stapling) limits the strength of the current evidence base. Overall, it is possible that LSG may be more appropriate as a first stage treatment in super-obese patients before the implementation of more definitive treatments (e.g. duodenal switch) instead of a stand-alone treatment. Based on the clinical need and the diffusion of this technique in Australia HealthPACT recommended that a more detailed Examination of this technology be commissioned.

Written by Luis Zamora, ASERNIP-S

Autologous bone marrow cell transplantation for myocardial infarction: Executive Summary

Heart failure is a disease characterised by a severe deficiency in ventricular pump function. It can arise from a variety of causes, however in western society its most common cause is myocardial infarction. Myocardial infarction itself is caused by the narrowing of epicardial blood vessels resulting from build-up of atheromatous plaque, which can lead to partial or total occlusion of vessels, creating imbalances in the oxygen supply and demand of the myocardium. In patients who have suffered myocardial infarction, a process known as myocardial remodelling, characterised by myocyte apoptosis, cardiomyocyte replacement by fibrous tissue in the ventricular wall, progressive expansion of infarct area and dilation of the left ventricular lumen, leads to heart failure.

Autologous bone marrow cell transplantation is designed to improve cardiac function and inhibit cardiac remodelling by replacing the fibrous scar tissue (created by myocardial infarction) with viable myocardium. The procedure involves the harvest of bone marrow cells and their delivery into the infarcted myocardial region. Harvest of bone marrow cells can be performed under general or local anaesthesia while delivery is performed under general anaesthesia by a cardiac surgeon.



Above: A bone marrow harvest.
(Printed Permission from The U.S. Navy.
U.S. Navy imagery used in illustration without endorsement expressed or implied)

Autologous bone marrow cell transplantation appears to be a safe procedure when cell transplantation is performed via either a transvascular approach or direct injection into the infarcted region. Few serious short term adverse events are associated with autologous bone marrow cell transplantation. Unfortunately transplantation via bone marrow cell mobilisation is associated with a high rate of restenosis making this option dangerous and much less favourable than the transvascular or direct injection transplantation approaches.

Autologous bone marrow cell transplantation has lead to significant improvements in various indicators of cardiac function in patients receiving cell transplantation via a transvascular approach. Transplantation via direct injection into the infarct-related region also demonstrated improvements in cardiac function but the positive effects were not as evident as the transvascular approach. Results were generally reported for short follow-up periods of 4-6 months. The long term benefits remain unknown.

Further investigation is required to determine the long term safety and efficacy of autologous bone marrow cell transplantation. This would indicate whether the significant short term benefits experienced by patients could be maintained over the long term and determine which group of patients stand to benefit the most from this potentially revolutionary treatment.

Written By Luis Zamora and Irving Lee, ASERNIP-S

Microvolt T-wave alternans for the identification of patients likely to benefit from ICD therapy in the prevention of sudden cardiac death

Only a small percentage of post myocardial infarction patients with low ejection fraction experience any benefit from an implantable cardioverter defibrillator (ICD). Given the high costs and procedural morbidity associated with ICD implantation, a strong emphasis has been placed on risk stratification techniques to determine patients that are likely to benefit most from ICD implantation. Microvolt T-wave alternans (MTWA) testing, a non-invasive measure strongly related to arrhythmic events, has shown promise as a risk stratification technique amongst patients with low ejection fraction.

HOW IT WORKS

MTWA testing has emerged as a promising risk stratification tool for determining which patients with low left ventricular ejection fraction should receive an ICD. MTWA refers to beat-to-beat changes in T wave amplitude and morphology, and has been closely linked to susceptibility to ventricular arrhythmias and SCD in a wide variety of patient populations[1,2,3]. A regular electrocardiogram cannot detect fluctuations in T-waves due to their small size, and thus the test requires specialised recording and signal processing methods. MTWA is recorded during a period of controlled exercise and later analysed using spectral decomposition methods. Two measures are obtained from the testing procedure, the magnitude of the T-waves (typically expressed in microvolts) and the alternans ratio, a quantity defined as the number of standard deviations by which the peak signal of the T-wave exceeds background noise. A positive test result is defined as alternans voltage of ≥1.9 μV at 0.5 cycles-per-beat and an alternans ratio of ≥3. A negative test result is defined as the absence of alternans at 0.5 cycles-per-beat when the heart rate is sustained at > 105 beats per minute for a period of at least one minute. Otherwise, the test is considered to be indeterminate[4].

THE EVIDENCE

Gehi et al (2005) conducted a meta-analysis (19 studies) of the value of MTWA in predicting future arrhythmic events[5]. A total of 2,608 patients across a wide range of populations were analysed in the study, including patients with congestive heart failure (CHF), ischemic CHF, non-ischemic CHF, post myocardial infarction, athletes and healthy participants. The mean age of participants in the studies ranged between 25 and 64 years, with a mean length of follow-up of 19-months. A negative MTWA test result was reported in 25 to 54 per cent of study subjects. A random effects model calculated a pooled positive predictive value for future arrhythmic events (classified as sudden cardiac death, cardiac death, ventricular fibrillation, ventricular tachycardia or ICD event) of 19.3 per cent (95% CI, 17.7%-21.0%), a pooled negative predictive value of 97.2 per cent (95% CI, 96.5%-97.9%) and a pooled relative risk of 3.77 (95% CI, 2.39-5.95). Sub-group analyses revealed no statistically significant differences in the predictive ability of MTWA testing between ischemic and non-ischemic patients. A significant difference in the PPV of MTWA testing between post myocardial infarction patients and CHF patients was reported however (6.0% vs. 25.5%, p <0.0001). No evidence of publication bias was found (p = 0.15).

FUTURE STEPS

A large number of studies have demonstrated the diagnostic effectiveness of MTWA testing in predicting future arrhythmic events across a variety of patient populations. MTWA testing appears to be a useful method for identifying which patients with ischemic or non-ischemic heart disease and left ventricular dysfunction are unlikely to receive benefit from ICD therapy. The technique is reported to be safe and convenient, and is currently reimbursed through Medicare in the United States for the purposes of risk stratification of SCD. Given the high rates of mortality associated with SCD and the availability of numerous high quality studies on MTWA testing, HealthPACT recommended that a full health technology assessment be conducted on this technology.

Written by Tom Sullivan, AHTA

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Other New and Emerging Technologies

The following additional technologies were considered by the Health Policy Advisory Council on Technology (HealthPACT) in January 2007.

- Versajet Hydrosurgery System for burns patients.
- PillCam ESO as an alternative for patients with oesophageal disease.
- Percutaneous radiofrequency ablation for osteoid osteomas
- Perioperative oxygen supplementation to prevent surgical site infections
- Polypropylene mesh for postoperative hernia prophylaxis
- Percutaneous aortic valve replacement for high-risk patients with aortic valve disease
- Low frequency ultrasound for wound debridement
- Totally endoscopic Coronary bypass surgery

The above technologies can be accessed on the following link:

http://www.horizonscanning.gov.au/internet/horizon/publishing.nsf/Content/asernip-s-net-s-summaries-2

- Home Studies for the diagnosis of sleep disorders
- Screening for Lung Cancer utilising computed tomography
- Electrochemotherapy for treatment of local malignant tumours by administration of chemotherapy drugs followed by electroporation
- Magnetic Resonance Imaging for Detection of Foetal Abnormalities
- Activecare DVT® for prevention of deep vein thrombosis and pulmonary embolism in high risk patients
- Rapid transcranial magnetic stimulation for stroke rehabilitation

The above technologies can be accessed on the following link:

http://www.horizonscanning.gov.au/internet/horizon/publishing.nsf/Content/prioritising-summaries-2006-2

PRODUCTION NOTES

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