Issue 4, September 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's activities continue at full pace with 20 summaries and three Reports being considered at the August meeting.

A number of point-of-care tests were discussed. These tests have the advantages of speed and convenience, but raise several ethical issues.

A number of genetic screening topics were also considered. Molecular pathology techniques allow multiple polymorphic genetic conditions to be tested. Testing may be cascaded to family members from an index case, as general population screening is not cost effective. HPACT recommended a full HTA for familial hypercholesterolaemia.

An interesting topic considered by HPACT was biodegradable coronary artery stents. Trials with different biodegradable stents were assessed, with reported outcomes such as the effect of material absorption and reduced interference with cardiac surgery in the future. However, it is apparent that anti platelet therapy is necessary. Whether this is required long term as in drug eluting stents or not is not yet known. HPACT will continue to monitor developments in this new technology.

An emerging technology bulletin covered the topic of DNA Microarrays. Gene profiling for multiple genes involved in disease, particularly cancer, and the subsequent prognostic indicators was discussed with great interest now that FDA has registered the first commercial test for this purpose. Although the technology holds great promise, it will need to be closely monitored for its impact on health care outcomes.

HPACT members have also participated in a 4-country survey (Australia, Canada, Finland and Italy) of values in new technology coordinated by Professor Devidas Menon. The survey assessed the importance of various attributes of new health technologies for different stake holders. and provided ranking on a number of attributes including safety, effectiveness, return to daily activities, cost, and newness. There was significant difference on the value of attributes according to the stakeholder perspective. Patients ranked return to daily activities, seriousness and a lack of alternatives highly. Effectiveness, cost and budget impact ranked lowly. Manufacturers were interested in return to daily activities, newness and a lack of alternative. Cost, seriousness and certainty of benefit ranked lowly. Health care policy makers ranked effectiveness and certainty of benefit and feasibility highly and return to daily activities and lack of alternatives lowly. Health care providers ranked a lack of alternative, seriousness and safety highly, and return to daily activities, newness and effectiveness lowly. Health care managers listed budget impact, convenience and immediacy highly, and a lack of an alternative and seriousness lowly. Overall effectiveness was found to be the most important attribute of a new technology, while newness the least.

With best regards,
Professor Brendon Kearney
Chair of HealthPACT

Quantitative electroencephalography (QEEG) for predicting patient response to antidepressants

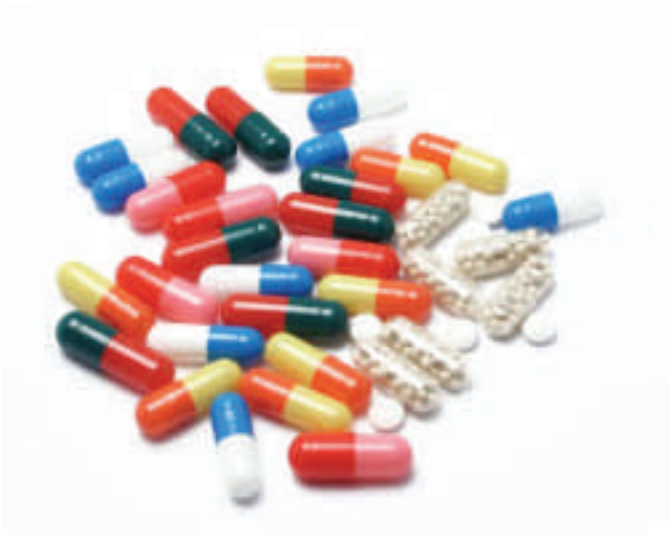
Cordance is a property derived from EEG signals using a specifically defined algorithm. It has been found to correlate with regional perfusion, which itself is a reflection of brain activity within that region. QEEG cordance data is used to assess whether a patient will respond to a specific antidepressant drug, at an early time point, before clinical signs of response/non-response are observable. This would facilitate the assignment of the patient to a therapy regimen which has the greatest likelihood of producing remission of depressive symptoms.

HOW IT WORKS

Electroencephalography (EEG) is the measurement of the electrical activity within the brain. It is non-invasive and does not require tracers or other contrast agents. In addition the equipment required is relatively small and inexpensive compared to other scanning techniques such as MRI or CT. The EEG signal data can be processed using a Fourier Fast Transform algorithm to calculate a power spectrum; this is known as Quantitative Electroencephalography (QEEG). The calculated cordance has been found to correlate with regional perfusion (blood flow), which in turn relates to the activity of the brain within that region[1].

THE EVIDENCE

Fifty one patients diagnosed with depression underwent a QEEG at baseline, and at 48 hours and one week after being placed on treatment of fluoxetine or venlafaxine (antidepressants) vs. placebo. The data were analysed for any changes that might predict the eventual response or lack of response to the medication or placebo. The patients were grouped, *post hoc*, into four categories, medication responders, medication non-responders, placebo responders and placebo non-responders. One factor that was significantly linked to medication response was a decrease in prefrontal cordance. At 4-weeks post-medication initiation there were clinically observable differences in prefrontal cordance between the response and non-response groups. And at eight weeks the patients with the greatest changes in cordance showed the best response to therapy. The authors concluded that cordance may be a predictive marker for response to antidepressant therapy[2]. Another study of 51 patients pooled data from two double-blinded placebo-controlled randomised controlled trials. It was found that the patients with the most favourable



neurophysiological response to the placebo, as measured by QEEG cordance changes, went on to have the best 8-week response to medication (fluoxetine 20mg or venlafaxine 150mg) after randomisation[3] (Hunter et al 2006).

FUTURE STEPS

The quality of the evidence for QEEG response prediction found in this summary is of average quality overall, and all the evidence suggests that early QEEG cordance can successfully predict the eventual "true" outcome of antidepressant therapy. A larger clinical trial, currently underway, will publish its results in the near future. Based on the potential usefulness of this technology for a large patient group, and the likelihood of further, higher quality evidence being made available in the near future, HealthPACT have recommended that this technology be monitored for 12-months.

Written by Adrian Purins, AHTA

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Bronchial Thermoplasty for Asthma Patients

Asthma is a chronic disease characterised by wheezing, tightness in the chest, and shortness of breath. The condition is caused by widespread reversible airflow obstruction and airway hyperresponsiveness[1]. Airflow obstruction can occur through narrowing of the airways as a result of smooth muscle contraction, mucus secretion, loss of mechanical support from surrounding parenchyma, chronic inflammation of the airways, or a combination of these[1,2].

HOW IT WORKS

Bronchial thermoplasty (BT) involves the application of controlled thermal energy directly to the airways through a bronchoscope with the aim of reducing the ability of smooth muscle to contract. This is achieved through a reduction in smooth muscle mass via coagulation of the bronchial tissue in airway walls where BT is applied[3]. Radiofrequency energy is delivered to the airway wall heating tissue to approximately 65°C, enough to reduce smooth muscle mass but avoid tissue destruction and scarring[4]. The Alair Bronchial Thermoplasty System consists of a bronchial catheter and radiofrequency generator. The catheter, designed to fit through the working channel of a standard bronchoscope, has an expandable four electrode basket with heating and temperature sensing elements[3].

THE EVIDENCE

The Asthma Intervention Research Trial examined the safety and efficacy of BT as a treatment for stable moderate or severe persistent asthma[5]. One hundred and twelve patients requiring daily therapy with inhaled corticosteroids (ICS) and long acting β_2-adrenergic agonists (LABA) in 11 centres across four countries participated. Patients were randomised to either BT (n = 56) or to a control group (n = 56).

The study was divided into a 4-week baseline period, treatment period of 6-9 weeks and 12 month follow-up period. The treatment period was the period during which BT group patients received three BT applications. The primary outcome was the difference in change in rate of mild exacerbations from baseline between the two groups. After 12 months, the mean number of mild exacerbations experienced per patient per week in the BT group declined, while control patients experienced a small increase. At three and 12 months (but not six months) the difference between groups in change from baseline was statistically significant (p = 0.03). The average number of exacerbations during the 2-week ICS only periods at 3, 6, and 12 months (compared to baseline) was significantly (p = 0.005) reduced in the BT group but not the control group (-0.16 ± 0.37 versus 0.04 ± 0.29 mild exacerbations per subject per week). Further statistical analysis revealed a significant difference between the groups (p = 0.001). This translated to approximately 10 fewer mild exacerbations per patient each year in the BT group. The mean number of *severe* exacerbations in the BT group was reduced at 12 months. However unlike *mild* exacerbations, control group patients also experienced a reduction. BT did not significantly reduce the number of severe exacerbations when compared to maintenance therapy alone.

During the treatment period, 407 adverse respiratory events were reported (control=106, BT= 301). Dyspnea, wheezing, cough, chest discomfort, night awakening and productive cough all occurred more frequently in the BT group ($p \leq 0.004$). Four patients required 6 hospitalisations in the BT group compared to two hospitalisations in the control group.

FUTURE STEPS

BT has the potential to provide relief of symptoms, better asthma control and decrease the level of airway hyperresponsiveness in patients who continue or have discontinued daily use of LABA. The technology has the potential of being used in conjunction with current medications to provide increased benefit to patients. Studies to determine the severity of asthma that would benefit most from this therapy and that evaluate the most suitable airways to provide the safest and most effective treatment are required. The long term consequences of the procedure are not known at this stage, therefore HealthPACT have recommended that this technology be monitored again in 12-months time.

Written by the staff at ASERNIP-S

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Genetic screening for familial hypercholesterolaemia: Executive Summary

Familial hypercholesterolaemia (FH) is characterised by chronically elevated serum cholesterol and low density lipoprotein-cholesterol (LDL-C) levels. FH is caused by mutations within the LDL receptor (LDLR) and apolipoprotein B (apoB) genes, resulting in dysfunctional LDL receptors which are incapable of clearing lipoproteins efficiently from the bloodstream. High concentrations of LDL-C and cholesterol are associated with early onset coronary heart disease.

FH is a common genetic disorder, affecting 1: 500 individuals worldwide. The prevalence rate in Australia and New Zealand is unknown but is likely to correspond to worldwide estimates. Although FH can be diagnosed early, research has shown that only approximately 20% of FH affected individuals have been diagnosed and only 7% are adequately treated.

Clinical diagnosis involves the measurement of total serum cholesterol levels and LDL-C levels, identifying the presence of tendinous xanthomas and a study of family history. Clinical diagnosis is, however, flawed. The range of serum

cholesterol and LDL-C levels in FH patients overlaps with that of normal individuals. Early studies conducted on children have shown misdiagnosis rates ranging from 4.5-19% when utilising total cholesterol or LDL-C cutoff points while other studies have reported that some FH-positive patients may not have sufficiently elevated levels of cholesterol for clinical diagnosis. In addition, studies have shown that tendinous xanthomas are not always prevalent in FH patients and are rarely present until the fourth decade of life. Therefore, the presence of tendinous xanthomas is not a reliable diagnostic criterion, especially in children.

Genetic testing of mutations within the LDLR or apoB gene has been advocated as an unequivocal diagnosis method for FH. However, the mutation detection rate can vary significantly, ranging from 20-80% in patients with clinically diagnosed FH. To date, no molecular technique is capable of detecting a mutation in all clinically diagnosed FH patients. It remains unclear as to what extent the low mutation detection rates are caused by the inadequacies of molecular testing, incorrect clinical diagnosis or the existence of polygenic mutations that result in the FH phenotype.

The Netherlands and Norway have established national genetic cascade screening programs for FH and have reported significant success. In the Netherlands, 93% of patients genetically diagnosed with FH had visited a physician and were prescribed lipid-lowering medication at 1-year post-screening, while 86% of patients remained on lipid-lowering medication at 2-years post-screening. LDL-C levels decreased by 30% at 2-years post-screening, with 66% of patients achieving LDL-C target levels of 135 mg/dl. The Norwegian screening program achieved 9.6% ($p<0.0001$) and 14.7% ($p<0.0001$) reduction in total serum cholesterol and LDL-C levels respectively at 6-months post-screening; while 24.1% of adult relatives had LDL-C levels of less than 135 mg/dl at 6-months.

Cost-effectiveness studies of cascade screening utilising genetic confirmation techniques have shown that the cost per life-year gained is comparable to cascade screening utilising conventional clinical diagnosis techniques. However, there is some controversy with regards to the cost per life-year gained for the Dutch screening program. It is important to note that none of these models are entirely appropriate for the Australia/New Zealand context.

In conclusion, genetic screening for FH appears to be effective in increasing the proportion of FH patients receiving adequate medical treatment; therefore resulting in significant reductions of LDL-C and cholesterol levels which should translate to lower incidences of coronary heart disease. It may be prudent to utilise clinical diagnosis to identify potential index cases; followed by genetic testing to identify the exact mutation causing the FH phenotype. When genetic testing is utilised for cascade screening of relatives, the results are encouraging.

Written by Irving Lee, ASERNIP-S

Intraoperative ultrasound for breast lesion localisation during breast conserving surgery: Executive Summary

Breast cancer is the most common invasive cancer diagnosed in females and is widely known as one of the leading causes of cancer death in females. The widespread use of mammography in the last 20 years as a means of screening has resulted in significantly higher detection rates for suspicious, non-palpable breast lesions. The localisation and excision (lumpectomy) of these non-palpable lesions is usually performed with the guidance of preoperative percutaneous mammographically-guided wire/needle localisation procedures such as needle localisation breast biopsy (NLBB). Although wire-guided localisation is generally recognised as an effective method; it is nevertheless associated with several drawbacks. The key concerns linked to the use of preoperative wire localisation are: *a)* accurate localisation and resection of the target lesion within a 3-dimensional space with the aid of a 2-dimensional localisation technique and *b)* the incidence of wire/clip migration. Studies have demonstrated that the miss rates of preoperative wire-guided localisation procedures vary from 0% to 22%, and clip migration up to 1cm from the target lesion can occur in up to 50% of patients. Approximately 20% of patients with malignant non-palpable breast lesions who underwent wire-guided localisation undergo a second surgical intervention to attain adequate margins.

Recently, intraoperative ultrasound (IOUS) is emerging as an alternative technique of localising nonpalpable breast lesions for excision and has been touted as an effective technique without the drawbacks associated with preoperative wire-guided localisation. IOUS does not require the insertion of a wire/clip and therefore eliminates the risk of wire/clip transection or migration while sparing the patient from the discomfort/distress associated with wire-insertion. More importantly, IOUS provides the surgeon with real-time imaging of the target lesion and therefore may potentially increase accuracy and ensure adequate margins in malignant cases.

One of the risks associated with the use of IOUS is its ability to reliably detect lesions. Studies have shown that approximately 40-60% of mammographically-detected lesions are visible with ultrasound; this therefore limits its applicability across a range of nonpalpable lesions. The second risk associated with the use of IOUS is inaccuracy resulting from the inexperience of surgeons with the use of ultrasound imaging. Researchers have proposed that surgeons who are at the early stages of their experience with ultrasound should be guided by a radiologist in the operating theatre until they are able to reliable detect all lesions themselves. With adequate training, surgeons can achieve comparable accuracy in localising and identifying lesions as trained radiologists.

Most of the identified studies demonstrated that the use of IOUS localisation achieves better negative margin rates compared to wire-guided excision. Only one study did not observe better margin clearance when utilising IOUS, but the results were comparable to conventional wire-guided localisation. Several studies also demonstrated that IOUS is associated with lower excision weight/volume compared to wire-guided excision. In addition, the use of ultrasound for *ex vivo* specimen analysis during surgery has been shown to be a more accurate method of determining adequate margins compared to specimen mammography.

The applicability of IOUS localisation was extended to non-ultrasound visible lesions with the introduction of a novel visualisation method that uses iatrogenically-induced haematomas. Both of the included studies which utilised this technique reported encouraging results, with IOUS attaining better negative margin rates and margin clearance while achieving similar or lower specimen resection volumes compared to conventional wire-guided excision.

At the time of writing, no cost-effectiveness studies on the utilisation of IOUS for nonpalpable breast lesion localisation have been conducted. Some of the included studies indicate that IOUS-guided lesion localisation does not result in substantially longer operative times compared to wire-guided localisation, while one study stated that operating room expenses did not differ significantly to standard excision in cases of palpable lesions. However, the cost of surgeon training and the required presence of a guiding radiologist in the early stages of utilising IOUS localisation were not discussed in the studies retrieved.

The evidence currently available on the use of IOUS-guided localisation of nonpalpable breast tumours lends substantial support to this technique and appears to be a potentially better technique to conventional wire-guided localisation. However, it is imperative that adequate training and supervision is provided to breast surgeons before this technique can be utilised effectively in patients.

Written by Irving Lee, ASERNIP-S

Biodegradable stents for patients with coronary artery disease who are undergoing percutaneous coronary interventions

Percutaneous coronary intervention (PCI) with coronary stenting is a widely utilised treatment procedure for patients with coronary artery disease. The main functions of coronary stents is to treat dissection and prevent restenosis. Studies have shown that coronary dissections are effectively contained by stent insertion and undergo a healing process, with the majority of coronary events occurring within the first 6 months. Similarly, restenosis has been shown to occur usually within the first 6 months. Therefore, there appears to be little benefit to have a permanent stainless steel stent in place beyond this time frame[1].

HOW IT WORKS

Permanent metallic stents are associated with complications including thrombosis which requires long-term treatment with antiplatelet therapy. Late complications associated with stent implantation, including in-stent restenosis, may be overcome with the use of biodegradable stents which dissolve to non-toxic substances after maintaining luminal integrity during the period of high-risk restenosis in the first 6 to 12 months after treatment[2]. In addition to this, biodegradable stents can be engineered to function as a large drug reservoir, allowing for the incorporation of larger amount of drugs compared to current drug-eluting stents[2].

THE EVIDENCE

Studies on biodegradable magnesium alloy stents, which contain small amounts of aluminium, manganese, zinc, lithium and rare earth elements, have been reported in several preclinical and peripheral vascular studies[3]; however studies on its application in coronary arteries have so far been limited to one multicentre trial[4] and case reports[5]. The prospective, non-randomised, multicentre trial (PROGRESS trial) was designed to evaluate the safety and efficacy of magnesium alloy stents in 63 patients with coronary artery disease and is the largest study to date on magnesium alloy stents. At 4-months post-stenting, all patients underwent a coronary angiogram and intravascular ultrasound examination. Clinical follow-up was repeated at 6- and 12- months. The investigators noted no deaths, cardiac deaths, fatal or non-fatal myocardial infarctions, or stent thrombosis during hospital stay up to 12 months post-stenting. At 12 months, a total of 16 patients (26.7%) experienced major adverse cardiac events. A significant increase in in-segment minimal luminal diameter ($p < 0.0001$) and a significant decrease in in-segment diameter stenosis ($p < 0.0001$) was reported immediately after stenting. Compared to QCA data immediately after stenting, 4-months follow-up results revealed that in-segment minimal luminal diameter decreased significantly while in-segment diameter stenosis increased significantly. Significant decreases were noted for proximal margin minimal luminal diameter, in-segment minimal lumen diameter, distal margin minimal luminal diameter; while a significant *increase* was observed for proximal margin diameter stenosis and in-stent diameter stenosis. Vessel reference diameter remained unchanged pre-stenting to 4 months post-stenting. The in-segment and in-stent restenosis rates at 4-months were 47.5 ± 59%.

With regards to the biodegradability of the stent, the investigators stated that no residual metal was detected by IVUS; indicating complete degradation and that in-stent thrombosis would be unlikely at later stages[4].

FUTURE STEPS

Biodegradable stents are in the early stages of clinical trials and long-term comparative results to bare metal stents are required before any conclusions can be made with regards to their efficacy and safety. Further studies are also required to determine the 'best' degradation duration, to demonstrate clinical efficacy, to ensure that the use of these stents results in substantial reduction in stent thrombosis rates compared to bare metal stents and to establish long-term safety. Health-PACT emphasise the experimental nature of these stents and the lack of any long-term data.

Written by the staff at ASERNIP-S

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DNA Microarrays: Executive Summary

The human genome consists of approximately 2.8 x10^9 nucleotide base pairs which may encode up to 25,000 genes. However not all of these genes are "turned" on, with only a subset being expressed at any one time. Not only can gene expression be turned on and off in response to stimuli, the amount or volume of gene expression can either be up or down regulated. The degree of gene expression may give previous unknown insights into the course of disease, and may guide treatment strategies.

DNA microarrays are a relatively new technology, which were first described in 1995. Small fragments of DNA, or oligonucleotides, are attached to a glass substrate by a variety of manufacturing processes. DNA microarrays may hold 100,000s of these elements. Complementary DNA from test and reference samples are labelled with a visualisation tag such as a fluorophore and hybridised to the microarray. The intensity of the signal of the bound DNA is an indication of a given gene's activity. Active genes will give a more intense, brighter signal than less active genes. Due to the large number of target elements able to be bound to a DNA microarray, the rapid, simultaneous characterisation of thousands of genes is possible. DNA microarrays may be useful tools in categorising diseases such as cancer by determining the presence or absence of particular genes, which may provide important biological, diagnostic and prognostic information.

This *Emerging Technology Bulletin* is aimed at providing a *non-systematic* overview of the rate of progress and development of DNA microarrays in Australia. It is not a definitive or comprehensive assessment of the safety and effectiveness associated with DNA microarrays. Although a great deal of research is conducted in Australia using DNA microarrays, no clinically orientated papers were identified for inclusion in this *Bulletin* that were published in Australia.

One of the significant areas in which the use of DNA microarrays has created great interest is in the detection of prognostic markers in breast cancer. Lymph node status still remains the best *prognostic* marker for survival, with 50 and 25 per cent of lymph node positive and negative women experiencing recurrence of disease, respectively. It has been estimated that up to 85 per cent of node-negative women may be undergoing toxic chemotherapy needlessly. It is hoped that with the use of DNA microarrays, women with a good prognosis, that is, those likely to be at low-risk of developing recurrence, can be easily identified and therefore avoid unnecessary adjuvant chemotherapy.

There are two breast cancer predictive DNA microarrays in current use. The MammaPrint® is the only FDA approved assay and utilises a 70-gene expression panel. The other assay, the 76-gene "Rotterdam" signature panel, is not a commercially available product. The MammaPrint® assay can be accessed by Australian women, at full cost to the patient, for A$3,600. Predictive DNA microarray studies indicate that both the 70-and 76-gene panels are capable of stratifying breast cancer patients into groups that either have a low-risk (good prognosis) or high-risk (poor prognosis) for the development of distant metastases, which will impact on their overall survival rate. Reported hazard ratios indicate that lymph node-negative women in the high-risk category are 2-5 times more likely to experience disease recurrence, even when adjusted for clinical prognostic factors. In addition, from this stratification it can be seen that a larger proportion of women considered to be at low risk of recurrence survive at 10-years than those at high risk. Only the studies conducted with the 76-gene panel reported on the sensitivity and specificity of using DNA microarrays, compared to the gold standard of bi-directional DNA sequencing, to predict recurrence of breast cancer. Reported sensitivities were good, ranging from 90-97 per cent for accurately predicting the risk of developing distant metastases within 5-years. However, reported specificities were poor, ranging from 31-48 per cent. Although the arrays successfully identify those patients at high-risk of recurrence, poor specificity indicates that a number of low-risk individuals are incorrectly categorised as high-risk and will receive chemotherapy needlessly.

All of the predictive breast cancer gene expression studies included for assessment in this *Bulletin* were retrospective. To date no prospective, randomised clinical trials, assigning

patients to chemotherapy regimes based on the results of gene expression assays, have been published. There are no data available which describe the impact of the 70-gene panel on patient outcomes (avoidance of toxic chemotherapy, disease-free survival and overall survival) by the identification of high (those who will benefit from adjuvant chemotherapy) and low risk women (those unlikely to benefit from adjuvant chemotherapy). To address these concerns, the MINDACT trial, is currently underway and actively recruiting node-negative women. This study is a prospective, randomised controlled trial, however results are not expected until at least 2011 due to the need to assess 5-year outcome measures.

Another area of great interest is the use of DNA microarrays to predict drug metabolism. Cytochrome P450 enzymes catalyse the oxidation of over 80 drugs and are encoded by a group of over 100 CYP genes. These genes are highly polymorphic, which may result in either an increase or decrease in enzyme activity. This in turn may affect the rate of drug metabolism and individuals may be classified as either an ultra-fast, extensive, intermediate or poor metaboliser of drugs. In 2004, the FDA approved the only DNA microarray (Affymetrix AmpliChip™ cytochrome P450 test) to investigate single nucleotide polymorphisms in two genes of particular interest: the CYP2D6 and CYP2C19 genes. Patients are assigned as either poor, intermediate, efficient or ultra-rapid metabolisers of drugs according to the combination of CYP alleles expressed.

AmpliChip™ appears to be an accurate means of genotyping patients into poor, intermediate, efficient and ultra-rapid metabolisers of drugs. High sensitivity (>99%) and specificity (>99%) of the AmpliChip™ relative to the gold standard indicate that the test can successfully identify individuals who are poor metabolisers. However, there is a lack of clinical data concerning whether or not genotyping patients has an impact on patient outcomes. No studies have been published that report on improvements in outcomes of patients on selective serotonin reuptake inhibitors (SSRIs), prescribed for non-psychotic depression, who have been genotyped versus those of patients on SSRIs who have not been genotyped.

DNA microarrays are a powerful research tool for the identification of association signals, as demonstrated by the large study conducted by the Wellcome Trust Consortium. This study has identified single nucleotide polymorphisms as being associated with some of the major public health diseases including coronary artery disease and diabetes. There is no indication of the attributable risk associated with these genes ie the proportion of all instances of these diseases that is associated with the identified single nucleotide polymorphisms. There are many other commercially available DNA microarrays (with European CE-marking *not* FDA approval) that are available for both human testing as well as pure research purposes.

"In-house" microarrays may be custom made and produced for $200, however an initial outlay of approximately $350,000 is required for basic equipment including a robotic spotter and laser scanner. Most Affymetrix microarrays require that they be processed using equipment purchased from Affymetrix. Costs for a complete microarray processing system are approximately A$335,000. Commercial gene expression arrays cost between A$270 -550 depending on the complexity of the target. The cost per array increases as the number of oligonucleotides per array increases.

In summary, although the possibilities for using DNA microarrays are vast there is a paucity of information regarding the use of gene expression data to give meaningful clinical outcome data. DNA microarrays have dramatically altered the ability to assess differences in gene expression on a mass, high-throughput scale. However, a great deal of work still needs to be done to translate knowledge gained from gene expression into meaningful patient outcomes

Written by Linda Mundy, AHTA

Other New and Emerging Technologies

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

- OraSure HIV Point of care testing
- Tam Pap for self testing of HPV
- Screening for hypertropic cardiomyopathy for identifying individuals at high-risk of sudden cardiac death
- NMP22 BladderCheck™ for diagnostic test for bladder cancer
- Vertebral assessment with dexa for screening for vertebral fracture during risk assessment for osteoporosis
- ZstatFlu® point-of-care influenza tests
- Niobe® magnetic navigation guidance system for percutaneous coronary interventions in patients with cardiac arrhythmias
- Implantable miniature telescope for the treatment of age-related macular degeneration

The above technologies can be accessed on the following link:

http://www.horizonscanning.gov.au/internet/horizon/publishing.nsf/Content/prioritising-summaries-2007-2

- Perioperative epirubicin, cisplatin and 5-fluorouacil chemotherapy for patients with resectable gastric cancer
- Polyflex® oesophageal stent for patients with oesophageal stenoses, fistulas and leakages
- Ovarian tissue cryopreservation and transplantation for patients with high risk of premature ovarian failure
- Anastamotic devices for coronary surgery
- Pumpless extracorporeal interventional lung assist (iLA) system (Novalung® GmbH, Hechingen, Germany)
- Percutaneous mitral valve repair utilising MitraClip(R) for patients suffering from severe mitral regurgitation
- Perutaneous aortic valve replacement for percutaneous implantation of a bioprosthetic valve in high-risk patients with aortic valve disease, without exposing them to risks associated with cardiopulmonary bypass and surgery
- Percutaneous Left Atrial Appendage Transcatheter occlusion (PLAATO) System to prevent thromboemboilsm in patients with atrial fibrillation
- Intracranial angioplasty and stenting (WingSpan™ self-expanding stent) for cerebral atherosclerotic stenosis

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

PRODUCTION NOTES

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