Issue 10, April 2009

ANZHSN Bulletin

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

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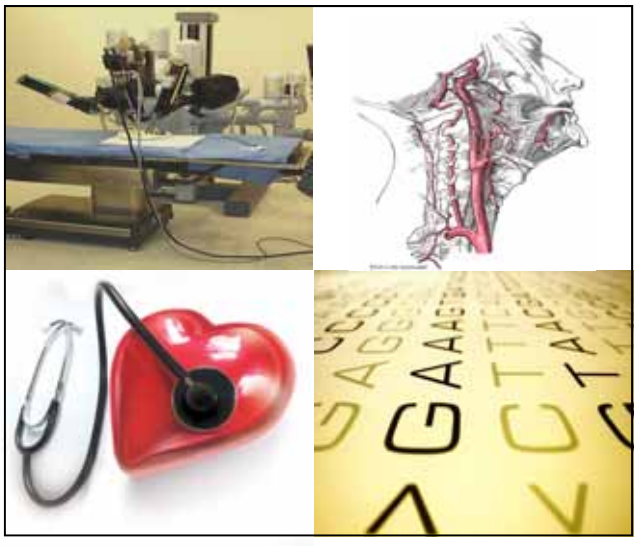
From the Chair's desk

The Department of Health and Ageing is managing a comprehensive evaluation of the BreastScreen Australia Program under the direction of the Australian Health Ministers' Advisory Council (AHMAC). HealthPACT was approached to undertake a Horizon scan on new and emerging technologies for breast cancer to inform this evaluation. An Emerging Technology Bulletin on *New and Emerging Technologies for Breast Cancer Detection* was prepared by AHTA and presented at the February HealthPACT meeting and is an example of the guidance provided to government policy by HealthPACT on important topics such as cancer detection and diagnosis. Further details on this Bulletin are available on page 6 of this newsletter. In addition, HealthPACT also considered 12 summaries and two other Horizon Scanning reports on *Embolic Protection Devises* and *Microvolt T-wave Alternans Test.*

The work of Euroscan continues with HealthPACT making a major contribution. The number of members is now twenty with Ireland and two agencies from the Italian Ministry of Health joining. One is a drug HTA agency from Verona and the other a device HTA agency from Rome. Euroscan has completed a toolkit on early warning of new health technologies which will be a very useful guide for any person or agency wishing to scan the horizon for new technologies. Linda Mundy and Janet Hiller of AHTA have made a significant contribution to this document which will be launched at the Singapore HTAi meeting.

The Annual HTAi meeting is in Singapore from June 21-24th - the meeting has an excellent selection of HTA topics - go to www.htai2009.org.

Professor B J Kearney
Chair, HealthPACT



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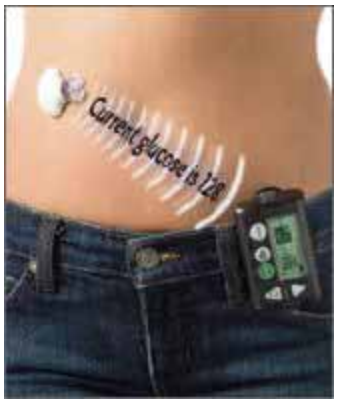
Continuous Glucose Monitoring for Diabetes in Pregnant Women

Pregnancy may be complicated by the presence of pre-existing Type I or Type II diabetes, or by the development of gestational diabetes. Although the Australasian Diabetes in Pregnancy Society (ADIPS) recommends diabetes screening for all pregnant women, this does not currently occur routinely in Australia (1). Diabetes during pregnancy increases the risk of pregnancy complications for both the mother and infant. Complications include foetal macrosomia, with the associated increased risks of birth trauma for both the infant and mother, higher need for caesarean section and other neonatal complications. Current standard practice for women with gestational diabetes involves up to seven finger-prick blood based tests per day. While this information is useful in patient management, it does not capture an accurate ongoing record of the subject's glucose levels at all points during the day.

HOW IT WORKS

The MiniMed continuous glucose monitor (CGMS) can provide up to 288 measurements over 72 hours, giving a far higher resolution record of glucose levels. The MiniMed device consists of a glucose monitor connected by a cable to the sensor which is inserted under the skin. The device records the level of glucose every 10 seconds and averages these measurements every five minutes. The patient's medical practitioner can then access the data and base any treatment changes on this higher resolution data.



Above: The MiniMed continuous glucose monitoring system (2).

THE EVIDENCE

A randomised controlled trial investigated the glucose control achieved by standard care versus continuous glucose monitoring with the MiniMed CGMS. The patient population was prospectively recruited and consisted of 71 pregnant women (46 with Type I and 25 with Type II diabetes). The women were randomised to standard care (n=33) or standard care plus continuous glucose monitoring (n=38). The data from the CGMS were not used for real time modification of treatment but one week after data collection was concluded the subject and medical staff were able to view the data and adjust behaviour accordingly. The outcomes for the intervention arm were a reduced level of HbA1c (indicating improved glycaemic control) in the third trimester, lower birth weight, and reduced risk of macrosomia. These factors indicate a better control of diabetes during pregnancy when monitored using the MiniMed CGMS (3).

The ability of the Minimed CGMS to monitor pre-gestational diabetic pregnant women was investigated in a prospective study (n=57, 40 Type I and 17 Type II diabetic subjects) conducted by Murphy et al (2007). The women were instructed to manage their diabetes as usual using finger prick blood glucose monitoring at least seven times a day. No direct comparison of the relative effectiveness of either the standard or Minimed methods was performed, however the CGMS provided greater knowledge about the changes in the subject's blood glucose levels over time. The higher resolution data provided by the CGMS demonstrated that women with Type II diabetes spend less time hypoglycaemic than Type I subjects ($p=0.04$), however both Type I and II women experienced the similar nocturnal hypoglycaemia episodes ($p>0.05$). Women with Type II diabetes also maintained the correct level of blood glucose for a greater proportion of the time than Type I women ($p=0.0001$) (4).

Another prospective cohort study has also been included for assessment in this summary (5).

FUTURE STEPS

The efficacy of continuous glucose monitoring has been reported in the past. The widespread introduction of CGM of *all* pregnant women would not be recommended, however, of importance is identifying the subgroup of pregnant women who would benefit from CGM. More research needs to be conducted on identifying these women and therefore HealthPACT has recommended that this technology be monitored for further information in 12-months time.

Written by Adrian Purins and Janet Hiller, AHTA

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EsophyX™ System

Gastro-oesophageal reflux disease (GORD) is a mechanical disorder in which a defective lower oesophageal sphincter does not close and stomach contents reflux into the oesophagus (1). The most common symptoms experienced by GORD sufferers include heartburn, regurgitation, dysphagia and chest pain. GORD can result in injury to the oesophagus leading to conditions such as reflux oesophagitis, oesophageal strictures, Barrett's oesophagus and oesophageal adenocarcinoma (2). Treatment for GORD generally follows one of two main pathways, pharmacological or surgical. The Nissen fundoplication procedure is the current gold standard treatment for GORD, with 89.5% of patients remaining symptom-free at 10 years (3).

HOW IT WORKS

Endoluminal fundoplication using the EsophyX device is a novel minimally invasive procedure. The procedure involves the insertion of the EsophyX device transorally, under direct endoscope visualisation, into the stomach to facilitate the reconstruction of the gastro-oesophageal valve (4). The result is a 3 cm to 5 cm long omega-shaped valve with a 200º to 310º circumference. The device facilitates the creation of the valve by drawing gastric tissue from the fundus between the body of the device and the tissue mould used to shape each portion of the gastro-oesophageal valve. Multiple polypropylene fasteners are then delivered across the moulded tissue to create a serosa to serosa flap 3 cm to 5 cm long. The repair of hiatal hernias is achieved through a proprietary oesophageal invaginator incorporated into the device, which engages the distal oesophagus at the level of the Z line.

THE EVIDENCE

Cadiere et al reported the results of a prospective multicentre study involving 86 patients suffering chronic GORD (median duration 6 years) undergoing daily proton pump inhibitors (PPI) therapy (median duration four years). The Endoluminal fundoplication (using the EsophyX device) procedure constructed valves measuring 4 cm (2-6 cm) and 230º (160-300º). At 12 months, the median GORD health-related quality of life (HRQL) reduction was 68%, which was statistically significant when compared to the baseline score ($p<0.0001$). At 12 months, the number of patients with a clinically significant reduction in GORD-HRQL score was 58 (73%). The number of patients in whom complete postoperative GORD symptom elimination had occurred (GORD-HRQL score ≤12) was 59 (75%) patients at 12 months. The median post-operative reduction in GORD-HRQL in comparison to the baseline scores (while on PPIs) was 22% at 12 months. At baseline, 8% of patients were taking a double dose of PPIs, 43% a full dose and 49% a half dose. At 12 months, 10% of patients were on full dose, 5% on half dose and 18% on demand, while 67% were no longer taking PPIs. Prior to the procedure, all patients were taking some sort of GORD medication daily. At 12 months, 12 (15%) patients required daily medication, 29 (37%) required occasional medication and 38 (48%) no longer required medication. After the procedure, all hiatal hernias (n=49) were successfully reduced. The lower oesophageal sphincter resting pressure was significantly improved by 53% ($p<0.01$) Oesophageal acid exposure time was significantly reduced or normalised in 43 (61%) patients at 12 months postoperatively. This was equivalent to a median percentage reduction in time pH < 4 of 33% at 12 months ($p=0.02$). In total, the procedure cured GORD in 56% of patients based on their symptom reduction and PPI discontinuation.

Three serious adverse events were reported, including two cases of oesophageal perforation during device insertion and one case of post-procedural intraluminal bleeding (5).

Two other case series with smaller sample size also indicated endolumenal fundoplication using the EsophyX device was safe and effective in treating symptomatic chronic GORD (3, 6).

FUTURE STEPS

Although there is limited evidence available on the use of the EsophyX device, due to the potential of the technology to provide a minimally invasive alternative to Nissen fundoplication HealthPACT have recommended that this technology be monitored for further information in 12 months time.

Written by Luis Zamora, ASERNIP-S

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LIPOchip for Genetic Diagnosis of Familial Hypercholesterolaemia

Familial hypercholesterolaemia (FH) is a common but under-diagnosed disorder that results in an almost 100-fold increased risk of coronary artery disease (CAD) (1). It is a genetic disorder resulting mainly from mutations in the low-density lipoprotein receptor (LDLR) gene that encodes the LDL receptor protein, or the apolipoprotein B (ApoB) gene. Other mutations in different genes are known but are very rare. Standard diagnosis of FH is performed using family history and blood lipid examination. This results in a *phenotypic* diagnosis of the patient which, due to other causes of hypercholesterolaemia, may not correlate with their genetic FH status.

HOW IT WORKS

The LIPOchip platform is based on a tiered mutation identification algorithm. Initially the patient is assessed using a microarray based mutation detection system. The microarray is designed to detect 203 mutations in the LDLR gene and four mutations in the ApoB gene. The subject's genetic material is extracted from a blood sample and assessed with a microarray. If the patient has any of the 207 mutations the subject is deemed FH positive. If the subject is negative their sample is subjected to a second tier of large genetic rearrangement analysis. If this tier is also negative then a third tier consisting of sequencing of the LDLR gene to assess the subject for novel mutations. If this step is also negative then the subject is deemed FH negative.

THE EVIDENCE

A study using the LIPOchip investigated 825 consecutive subjects attending three Spanish lipid clinics. Subjects were suspected of having FH due to: very high familial total or LDL cholesterol levels; possible family history of premature CAD; and possible tendon xanthomas (subcutaneous depositions of fat associated with tendons, especially the Achilles tendon, or those of the hands and feet; caused by severe hypercholesterolaemia). The version of the LIPOchip used screened for 203 mutations in the LDLR gene and four in ApoB. Subjects who had negative results were subsequently assessed for large genetic rearrangement analysis. If they were negative for this also, then genetic sequencing of the promoter, 18 exons and flanking introns was performed to uncover new mutations. Overall 459 subjects were found to have FH-causing mutations. Those who were positive for mutations were found to be more likely to have a family history of tendon xanthomas (OR 7.779 (95% CI [3.639–16.712])), more likely to have tendon xanthomas (OR 3.675 (95 % CI [1.583–8.528]), and

more likely to be female (OR 1.966 (95 % CI [1.059–3.649])). No problems were reported with using the LIPOchip (2).

A second study by the same researchers investigated the overlap of FH with familial combined hyperlipidaemia (FCH). The population consisted of 143 FCH patients from two Spanish lipid clinics. These subjects could be classified as FH clinically and thus were investigated using the definitive genetic analysis provided by the LIPOchip. Mutations in the LDLR gene were discovered in 28 (19.6 %) of FCH subjects. This indicated that there is some diagnostic overlap of these two disease types and may explain why some FH patients present with high triglycerides (2).

FUTURE STEPS

A number of diagnostic genetic tests for familial hypercholesteraemia are likely to come on to the market in the near future. HealthPACT recommends that all genetic tests for FH, including the LIPOchip, be monitored for further information in 12-months time.

Written by Adrian Purins and Janet Hiller, AHTA

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T-Stat Ischaemia Detection System

Ischaemia is the inadequate supply of blood to a tissue, resulting in damage to the tissue due to a lack of oxygen and the subsequent built up of metabolic waste. Reduced blood flow can occur due to several factors such as compromised cardiac function, blood vessel constriction or blockage, or changes to local blood flow. Ischaemia is an important clinical consequence of many surgical and medical procedures and a variety of medical conditions including atherosclerosis which may lead to mesenteric ischemia.

HOW IT WORKS

The T-Stat system uses reflectance spectroscopy to measure the level of oxygen saturated haemoglobin in tissues. Oxygenated and deoxygenated haemoglobin have different absorption spectra under visible light, which can be used to calculate their relative concentrations. Visible light is used to illuminate a tissue through an optical fibre. Detection optical fibres gather the reflected light and pass it to a spectrophotometer where absorption is measured and the level of oxygen saturated haemoglobin in the tissue can be calculated. The T-Stat has several probes available for different applications including buccal or gastro-intestinal monitoring.

The T-Stat monitor with buccal probe and endoscopic catheter.

Images used with permission of Spectros Corporation.

THE EVIDENCE

A preliminary study investigated the T-Stat in pigs and human subjects. The pig model was used for validation of the device. The human arm of the study investigated normoxia, hypoxia, and local ischaemia. In a total 111 patients (733 measures), the mean normoxic tissue oxygen saturation (StO_2) levels at enteric mucosa, skin, and buccal mucosa were 69±4%, 72±16%, and 77±3%, respectively. The StO_2 levels at oesophageal mucosa were 56±6% during hypoxemia. While the mean StO_2 dropped from 73% at baseline to 34% 120 seconds after partial occlusion ischemia, and to 8% 120 seconds after total occlusion ischemia. (1).

Another study investigating open repair (n=5) or endovascular aneurysm repair (EVAR) (n=20) of abdominal aortic aneurysm (AAA) used the T-Stat system to monitor colon mucosal oxygen saturation (CMOS) during surgy. The buccal mucosal oxygen levels were used as a comparator to verify the CMOS values were truly local values and not a reflection of systemic oxygen levels. It was discovered that CMOS levels decreased from the baseline 56±8% to 26±17% ($p<0.0001$) during infra-renal aortic balloon occlusion and femoral arterial sheath placement in EVAR. A reduction in CMOS level from pre-surgical 56±9% to 15±19% ($p<0.0001$) was observed when the infra-renal aorta and iliac arteries were clamped during open repair. In both EVAR and open repair, CMOS returned to baseline levels at 6.4±3.3 minutes after aortic circulation restoration. It was also reported that simultaneous buccal mucosal oxygen saturation was stable (82±6%) during aortic manipulation. No T-Stat system-related adverse events were reported in this study (2).

Once case report of EVAR which evaluated the T-Stat for colon ischaemia diagnosis has also been included in this summary (3).

FUTURE STEPS

Although there is only limited, preliminary evidence on the use of the T-Stat system, it may be useful to inform targeted resuscitation decision making. Therefore HealthPACT recommend that this technology be monitored for further information in 12-months time.

Written by Adrian Purins and Janet Hiller, AHTA

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New and Emerging Technologies for Breast Cancer Detection (Executive Summary)

A comprehensive evaluation of the BreastScreen Australia Program has been conducted, under the direction of the AHMAC and managed by the Department of Health and Ageing. To inform this evaluation, DoHA requested that Health PACT undertake a Horizon Scan on new and emerging technologies for the screening of breast cancer.

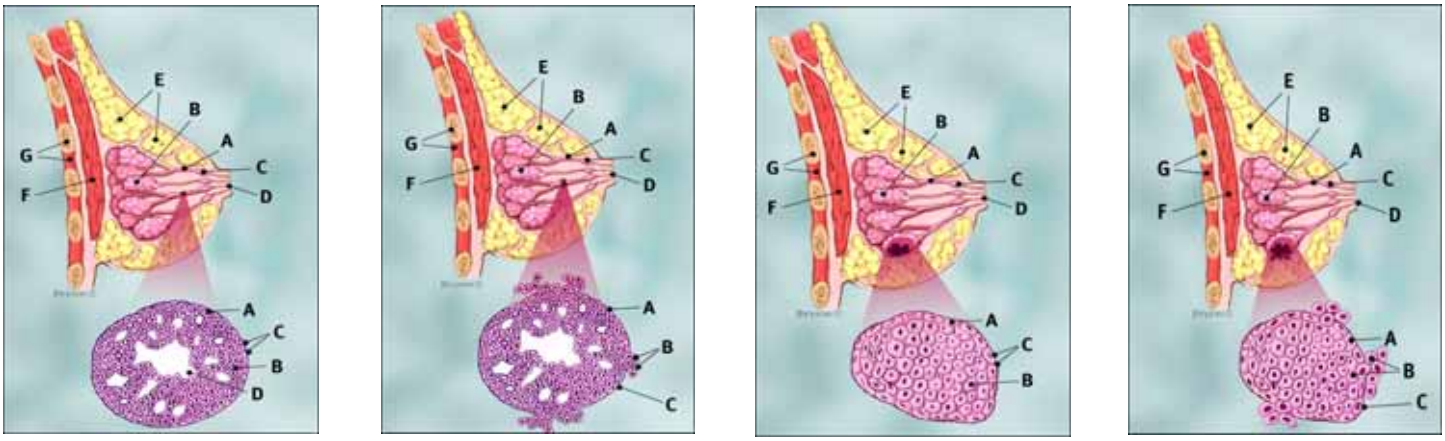
The aim of this Emerging Technology Bulletin was to identify any new and emerging technologies for the early detection of breast cancer, not previously examined in HS summaries or reports and to give a brief but non-systematic overview on the current available evidence on these techniques.

Direct evidence of a reduction in breast cancer mortality due to screening can only be generated by large scale, long-term (5-10 years) prospective randomised controlled trials with mortality as an outcome or endpoint. Trials such as this as are expensive and require substantial infrastructure. Surrogate endpoints such as diagnostic accuracy of a screening modality and cancer detection rate are often used, and inferences are made in respect to the impact that such endpoints may have on mortality in a screening environment.

Mammography is considered an imperfect screening tool, as it is neither highly sensitive nor highly specific. The 2006 Cochrane review by Gotzsche and Nielsen reported mammography to have a sensitivity ranging between 71-79 per cent, meaning that between 21 and 29 per cent of breast cancers are false negatives and are missed at screening. Although mammography has its limitations, there is no doubt that, with the introduction of the universal mammography program offered by BreastScreen Australia for women aged 50-69 years, that the mortality associated with breast cancer has declined over time and with increased community participation.

This Emerging Technology Bulletin identified 7 technologies used for the detection of breast cancer: computed tomography, positron emission tomography, ultrasonography, thermography, electrical impedance, scintimammography and ductoscopy. In addition this Bulletin gave a brief description of 3 future technologies which may not be of clinical value within a 5-year time frame: volatile organic compound breath tests, radar-based microwave imaging and optical coherence tomography; 2 of which are being investigated by researchers in Western Australia. Finally, the use of prognostic indicators or risk assessment tools for breast cancer were described.

Few studies reported on the use of technologies in a truly asymptomatic population. By screening a symptomatic population, the "prevalence" of the disease is artificially increased, the number of true positives detected by the test will increase as will the positive predictive value, giving a false impression of the accuracy of the test in a screening population. Screening programs can be conducted in high-risk populations to maximise yield, however for breast cancer detection in Australia this should occur in women in the age group 50-69 years rather than symptomatic women.



Above: Types of breast cancer.
Image 1: dual carcinoma in situ; Image 2: invasive ductal carcinoma; Image 3: lobular carcinoma in situ; Image 4: invasive lobular carcinoma
A: ducts; B: lobules: C: dilated section of duct to hold milk; D: nipple; E: fat; F: pectoralis major muscle; G: chest wall/rib cage

Image used with the permission of Breastcancer.org
(http:www.breastcancer.org/pictures/types/)

New and emerging technologies for breast cancer detection (continued...)

Of concern are technologies that are available in Australia on a direct-to-market basis which do not require regulatory control by the TGA and can therefore be offered to women of all ages. Currently thermography and electrical impedance are offered to Australian women on a user pays basis. Direct marketing to consumers may have social consequences, such as increasing the burden on the health care system to cope with false positive or false negative test results. For example a large number of false positive tests may result in an increase in the number of mammograms performed, especially in women younger than the specified mammographic screening target range of aged 50-69 years. There is a significant ethical dimension to the subjecting of people, albeit purportedly of their free will, to investigations which may not have as good sensitivity and/or specificity as diagnostic modalities employed in the mainstream health system following methodologically rigorous, research-based assessment and active involvement of consumer interests. Clearly these pivotal interests have determined a high level of expectation around the process of informed consent in the context of screening tests, and the community expectation that this process should be applied consistently, whatever the modality, and setting and the payment arrangements of the screening process.

Extensive research is currently being conducted to identify factors, biomarkers or genetic markers that may be of potential use for the assessment of a woman's risk of developing breast cancer. This may in turn enable medical practitioners to provide suitable medical, psychological or surgical management appropriate to a woman's needs. However, it should be stressed that these factors are surrogate markers that are associated with an increased risk of developing disease, and as such results of marker studies are not diagnostic and should be treated with caution. The results of prognostic tests may result in increased surveillance of women considered to be at elevated risk, which may in turn lead to earlier detection of disease.

In summary, it is clear from the studies included for assessment in this Bulletin, that to draw any meaningful conclusions regarding the potential of new breast cancer diagnostic technologies, larger, long-term studies of appropriate study design need to be conducted in asymptomatic women. Mammography may be considered an imperfect screening modality, however the addition of MRI for high risk women and the roll out of digital mammography have increased the options available to women in Australia. Only a brief snap shot of the diagnostic capabilities of the new technologies included in this Bulletin have been presented. An in-depth analysis of the level of training, infrastructure and financial support required to become proficient at conducting diagnostic testing and interpreting the results of these new technologies was considered to be beyond the scope of this Bulletin, but remains an important concern.

Written by Linda Mundy, Vivian Liufu, Annette Braunack-Mayer, Tracy Merlin and Janet Hiller, AHTA

For a full reference list see www.horizonscanning.gov.au

NEWS FLASH

AHRQ has released a new evidence report that found insufficient evidence to indicate whether one test method is superior to others when evaluating the status of patients' human epidermal growth factor receptor-2 (HER2) gene. Evidence is lacking because best practices for tissue processing and guidelines on different laboratory test methods to evaluate HER2 have only been recently standardized.

The report, *HER2 Testing to Manage Patients with Breast Cancer or Other solid Tumors*, was produced by AHRQ's Blue Cross and Blue Shield Association Evidence-based Practice Center in Chicago and can be accessed from http://www.ahrq.gov/downloads/pub/evidence/pdf/her2/her2.pdf.

Transoral Robotic Surgery (TORS) for Head And Neck Cancer

Head and neck cancer is a general term used to describe a group of cancers which originate from the upper aero-digestive tract (including the lip, mouth, nose, paranasal sinuses, pharynx and larynx). The majority of these cancers originate from the mucosal lining of these different parts of the upper aerodigestive tract, and tend to be squamous cell carcinomas. Treatment of head and neck cancer usually involves some form of surgery, including open head and neck surgical resection or transoral approaches such as transoral endoscopic laser surgery. One of the major obstacles to the removal of cancers of the head and neck through the oral cavity has been limited access to the area (1).

HOW IT WORKS

Transoral robotic surgery (TORS), which is defined as surgery done via the oral cavity that uses a minimum of 3 robotic arms and allows for bimanual surgical techniques (2), has the potential to improve accuracy for surgeons and lessen the scarring, breathing problems, damage to speech and post-operative pain associated with treating head and neck cancers. The da Vinci Surgical System (Intuitive Surgical Inc.) that is currently used in TORS, is composed of a console at which the surgeon is seated at a distance from the patient, a surgical cart, and four robotic arms (three laterally placed instrument-holding arms and a fourth centrally placed arm with an endoscope) that are controlled by the surgeon's movement of handles in the console (3).

THE EVIDENCE

A prospective phase I clinical trial examined the feasibility of TORS for radical tonsillectomy in patients with previously untreated cancer of the tonsillar region. TORS radical tonsillectomy, using the da Vinci Surgical System, without free-flap reconstruction was performed in 27 adult patients for previously untreated invasive squamous cell carcinoma of the tonsillar region. In this study, TORS was successfully performed in all 27 patients, and all robotic arms functioned optimally during surgery, with no observed interference between the arms. Ninety per cent (25/27) of patients achieved final margins that were negative for cancer. All 27 patients underwent percutaneous gastrotomy, and 96% (26/27) of patients were able to swallow without the use of a gastrotomy tube at last follow-up. No surgery related-mortalities were reported. Operative complications occurred in 19% (5/27) of patients: two experienced moderate trismus; one had hypernasality; one experienced delirium tremens; and the fifth patient had mucosal bleeding and postoperative trachea swelling (1).

A more recent prospective study examined the technical feasibility, safety and efficacy of TORS (using da Vinci Surgical System) in a total of 20 adult patients with a range of malignant head and neck cancers, including the oral cavity, oropharynx, hypopharynx and larynx. In 2 patients, access to the tumour was inadequate and the procedure was terminated, thus TORS was able to be successfully performed in 90% (18/20) of patients. Intraoral reconstruction was performed in 9 patients. Fifteen (83.3%) patients with squamous cell carcinoma underwent concomitant unilateral (n=10) or bilateral (n=5) selective neck dissections immediately after surgery. At last follow-up (>6 months) there was no evidence of recurrence in any of the patients who underwent TORS. No complications occurred intraoperatively or postoperatively (4).

Above: The da Vinci Surgical System.

Source: http://commons.wikimedia.org/wiki/File:Laproscopic_Surgery_robot.jpg

FUTURE STEPS

Based on the potential of TORS as well as other techniques which make use of the da Vinci surgical system HealthPACT have recommended that all procedures which make use of the da Vinci system be monitored in 12-months.

Written by Prema Thavaneswaran, ASERNIP-S

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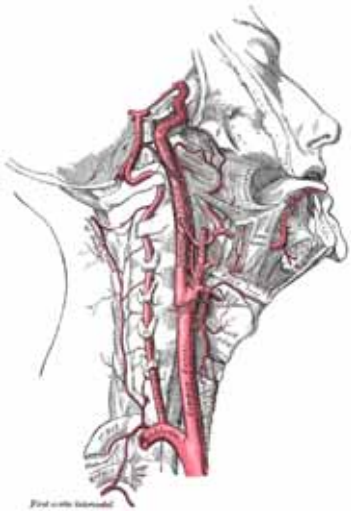
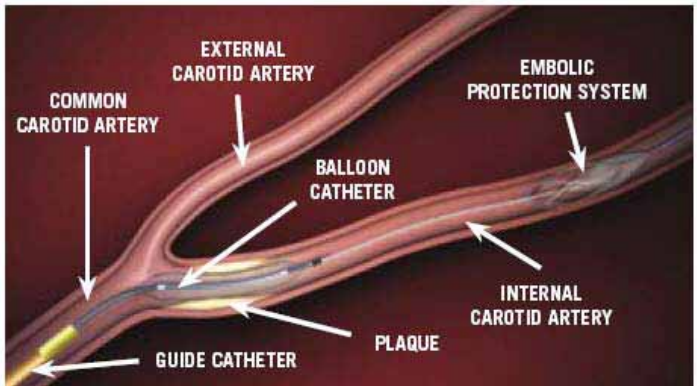
Filter-type Embolic Protection Devices for Carotid Artery Stenting (Executive Summary)

The rapid adoption of carotid artery stenting (CAS) for the treatment of carotid stenosis, particularly after the introduction and regulatory approval of embolic protection devices (EPD), has been a point of debate between some clinicians and researchers. Although the use of EPDs during CAS to prevent embolic events makes intuitive sense, some researchers have highlighted that the evidence supporting the effectiveness of EPDs is limited. A major point of contention is that due to the endorsement of EPDs by regulatory bodies, the support for the use of EPDs has risen exponentially despite the paucity of evidence. Some researchers have also highlighted that the pivotal SAPPHIRE trial, which led to regulatory approval of EPDs, was severely flawed.

This horizon scanning report attempts to discuss the evidence available on the effectiveness of EPDs, particularly filter-type EPDs that are widely utilised, accounting for 90% of all protected CAS procedures. The evidence retrieved does not support the general perception that EPDs are absolutely necessary during CAS to reduce the incidence of neurological events or death due to emboli. The only randomised trial to date which compared protected and unprotected CAS did not demonstrate any advantages when EPDs are utilised. Five of the seven comparative studies retrieved to discuss the effectiveness of EPDs did not support the general concensus that EPDs significantly reduce stroke and death rates. Only one study demonstrated that the use of EPDs can significantly reduce adverse event rates. Although the remaining study reported a substantial drop in adverse even rates, it was not sufficient to achieve statistical significance. Diffusion weighted imaging indicated that the incidence of new ischaemic lesions after protected CAS ranged from comparable to significantly higher relative to CAS without EPD protection. Meanwhile, doppler ultrasound analysis in another study suggests that the use of EPDs may result in greater microembolic load although this did not translate to he incidence of more neurological events.



Above: Illustration of the carotid artery



Above: Illustration of filter-type embolic protection system (ACCUNET™)

Image used with the permission from the Institute for Advanced Medical Education

Comparisons between the different classes of EPDs did not reveal any differences in terms of safety or effectiveness. However, one study highlighted that perhaps concentric filter EPDs may be more effective compared to eccentric filter EPDs, at least in symptomatic patients. The cost-effectiveness of EPDs remains unknown.

Overall, the supporting evidence for the use of EPDs (at least filter-type EPDs) appears to be limited. Despite compelling evidence from manufacturer-sponsored trials, the majority of comparative studies did not demonstrate the purported significant reduction in stroke or death rates implied in non-comparative trials and registries. Further studies are warranted, despite the fact that randomised trials are unlikely to be conducted due to the established perception that EPDs are mandatory. In addition, more studies examining the use of patient-tailored EPDs based on pre-operative characteristics should be initiated.

Written by Irving Lee, ASERNIP-S

For a full reference list see www.horizonscanning.gov.au

Microvolt T-wave Alternans Test (Executive Summary)

Recently there has been a marked increase in the use of implantable cardioverter defibrillators (ICDs) in a variety of patient populations in Australia and New Zealand. At a cost exceeding AUD$50,000 per defibrillator the finding that only a minority of defibrillators are ultimately required to discharge is of interest. At present there is no definitive prognostic tool used to risk stratify patients who are suitable for implantation with an ICD, and in whom the defibrillator will be required to discharge. The microvolt t-wave alternans (MTWA) test has been suggested as one such tool which could assist physicians in the decision of whether or not to implant an ICD. The MTWA test measures small beat-to-beat fluctuations in the t-wave not detectable through routine ECG and therefore requires specialised sensors combined with computer algorithms to evaluate results. A MTWA test result can be positive, negative or indeterminate, with negative test results reported to assist in identifying a low-risk subgroup of patients who actually receive no benefit or net harm from ICD therapy.

There was one systematic review conducted on this topic in 2005 (Gehi *et al*). This Horizon Scan summarises the results of that review and subsequently summarises the findings of MTWA studies undertaken since then. The meta-analysis conducted by Gehi included 19 studies of the MTWA test conducted using exercise as the stressor and examining various patient populations. This study found that the presence of significant MTWA predicted nearly a four-fold risk of ventricular tachyarrhythmic events compared to the absence of significant MTWA. It should be noted that the primary analysis excluded indeterminate MTWA test results, only comparing positive and negative patients. This is important because since then it has been shown that positive and indeterminate results can be grouped into an 'abnormal' test category.

In addition to the systematic review, a further 11 prospective cohort studies (Level II prognostic evidence) met the inclusion criteria for this Horizon Scan. The included studies were generally NHMRC level II prognostic studies of good quality providing sufficient detail on recruitment and selection, patient characteristics, methods of conducting and analysing the MTWA test, and relevant outcomes. Overall, the MTWA test was found to have a high negative predictive value (NPV) ranging from 93% to 100%. This high NPV led researchers to conclude that, after adjustment for confounding factors, the MTWA test is useful for the risk stratification of cardiac patients prior to ICD implantation. However, despite the positive overall conclusions,

there is still some concern around cardiac events occurring in patients who have an MTWA negative/normal result, given the morbidity and mortality associated with such events.

It is probable that if the MTWA test was to become widely available in Australia and New Zealand, the test results would be considered by clinicians in addition to, rather than as a replacement for, other cardiac clinical investigations such as LVEF. The ultimate value of the MTWA test in clinical, economic and financial terms will be determined by the willingness of the clinician to act upon the MTWA test result, either alone or in combination with other prognostic information.

Written by Dan Paech, Kristina Coleman and Adèle Weston, HSAC

For a full reference list see www.horizonscanning.gov.au

Other New and Emerging Technologies

The following additional technologies were considered by the Health Policy Advisory Committee on Technology (HealthPACT) in February 2009.

- Dermagold™ shock wave therapy to treat patients with soft tissue wounds.
- Autofluorescence imaging for colonoscopic adenoma detection for the increased detection/removal rate of adenoma during colonoscopic screening in patients at risk of adenoma or colorectal cancer.
- Percutaneous compression plate for minimally invasive treatment of patients with intertrochanteric hip fractures.
- Totally endoscopic coronary artery bypass surgery (da Vinci System) for patients suffering from coronary artery disease.

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

Further information on the health technologies included in the Bulletin can be accessed on the following link:
http://www.horizonscanning.gov.au

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Australian Government
Department of Health and Ageing

AHTA
Adelaide Health Technology Assessment

PRODUCTION NOTES

The ANZHSN Bulletin is published by Adelaide Health Technology Assessment (AHTA) on behalf of the Health Policy Advisory Committee on Technology (HealthPACT) and funded by the Australian Government Department of Health and Ageing.

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