HealthPACT, the Horizon Scanning Subcommittee of MSAC which oversees horizon scanning work for Australia and New Zealand continues to be very active. At the October meeting, 12 new or revised prioritising summaries were considered and two new horizon scanning reports.

The horizon scanning report on sleeve gastrectomy as a single stage bariatric procedure was the subject of considerable discussion. There is level two evidence with trials of small numbers that suggest that sleeve gastrectomy may be effective and cost effective when compared with the most common bariatric surgical procedure in Australasia for weight loss and reduction in BMI, lap banding. Whilst there appear to be advantages as always, there are some down sides in that the procedure is irreversible, has more serious but less frequent complications than other procedures and can not be adjusted as with other bariatric surgery procedures. Long term data on this procedure is yet to emerge, but short term results are encouraging. Health services will need to carefully address governance issues (credentialing, scope of practice and audit if embracing any form of bariatric surgery.)

Recently representatives of HPACT attended EuroScan, the international association of horizon scanning agencies. Australia will be well represented through the vice presidency from January 2008 of EuroScan. There are now 15 members of EuroScan, the majority from the European Union and the remainder from other countries including Canada, the UK and Australia. EuroScan is supported by a secretariat located in the University of Birmingham, UK. The secretariat collates the work of all member agencies and coordinates the EuroScan website -

The Australian Department of Health and Ageing is reviewing health technology organisations in line with the Productivity Commission’s recommendations. Horizon Scanning will be included in this review. We would welcome comment, opinion or suggestion on the value and the role of horizon scanning in Australia and New Zealand. Please feel free to make these comments on the HPACT website -

With best regards,
Professor Brendon Kearney
Chairman of HealthPACT
Multi-catheter interstitial brachytherapy

Breast conservation therapy, consisting of breast conserving surgery (partial mastectomy or lumpectomy) followed by whole breast irradiation, is the standard of care for women with early stage breast cancer (stage 0, I and II)\(^1\). Radiation therapy was incorporated into breast conservation therapy to reduce the risk of local tumour recurrence\(^2\). In whole breast irradiation, radiation is delivered to the whole breast five days a week for approximately six to seven weeks\(^3\). Accelerated partial breast irradiation using multi-catheter brachytherapy is an alternative to whole breast irradiation for women with early stage breast cancer who require breast conservation therapy.

**HOW IT WORKS**

In accelerated partial breast irradiation (APBI), radiation is only focused on the area of partial mastectomy (plus an additional margin of 1 cm to 2 cm), which has the greatest likelihood of tumour recurrence\(^4\,^5\). This approach not only offers the patient increased convenience, but also decreases the amount of radiation delivered to the breast and surrounding vital structures\(^5\).

The most common method of delivering APBI is multi-catheter interstitial brachytherapy, which delivers a homogenous dose of radiation in a short space of time to the tumour bed\(^2\). Multi-catheter interstitial brachytherapy involves the temporary placement of 10 to 20 flexible catheters in the portion of the breast around the partial mastectomy cavity either intra-operatively or postoperatively\(^6\). High dose rate (HDR) radiation treatment is then administered in 30-minute sessions twice daily on an outpatient basis, with approximately 3.4 gray (Gy) being delivered per session over five days (total radiation 34 Gy). Low dose rate (LDR) treatment involves the delivery of approximately 45 Gy to the target area over five days on an inpatient basis\(^6\). This compares to approximately 50 Gy delivered during whole breast irradiation\(^1\).

**THE EVIDENCE**

One hundred and fifty eight women with stage I/II breast cancer and gross total resection of the primary tumour were prospectively enrolled to undergo one of three brachytherapy protocols\(^6\). The three protocols were: LDR brachytherapy delivering 50 Gy over 4 days; HDR brachytherapy delivering 32 Gy in eight fractions; and 34 Gy in 10 fractions. Of the 199 patients, 5 had an ipsilateral breast tumour recurrence, which is equivalent to a five-year recurrence rate of 1%. In 79 patients who were followed up for a minimum of five years, cosmetic results were rated as good or excellent by 99% of patients. There were no statistically significant differences between the groups with respect to five-year actuarial rates of distant metastases, disease-free survival, overall survival, or cause-specific survival.

A comparative study of interstitial brachytherapy in 50 women undergoing breast conservation therapy that included lumpectomy and axillary lymph node dissection was conducted\(^7\).

Alternating groups of 10 patients were treated with either LDR or HDR brachytherapy. A comparative analysis of the control and brachytherapy groups at approximately 74 months revealed one local failure and three regional nodal recurrences in the brachytherapy group (8% recurrence rate) and five local failures in the control group (5% recurrence rate; \(p > 0.05\)). While the difference in local failure and total recurrence rates between groups was not statistically significant, regional recurrences among brachytherapy patients were significantly lower compared to the control group (\(p = 0.04\)). At the last follow-up (time not stated), 88% of brachytherapy and 92% of control patients were disease free.

**FUTURE STEPS**

Evidence from two non-randomised comparative studies indicates that patients with early stage breast cancer who undergo breast conservation therapy with multi-catheter interstitial brachytherapy have similar rates of ipsilateral breast tumour recurrence compared to those treated with whole breast irradiation. However, further research is needed to determine which of the two treatment regimens, LDR or HDR, is the most effective. Based on the potential uptake and rapid diffusion of this technology, HealthPACT recommended that it should be monitored for further safety and effectiveness evidence in 12-months time.

Written by Luis Zamora, ASERNIP-S

**REFERENCES**

This report describes the use of MRI to detect foetal abnormalities or birth defects. Currently the Australian National Perinatal Statistics Unit defines a birth anomaly as “anatomical defects or chromosomal abnormalities that are present at birth”.

The use of MRI is not designed to replace ultrasound as the obstetric diagnostic tool of choice, but rather to act as an adjunct in cases where an ultrasound diagnosis is equivocal. Ultrasound remains the gold standard of foetal imaging.

MRI is considered a suitable foetal imaging technology as it is non-invasive, avoids the use of ionising radiation, and is not hampered by maternal obesity or foetal position. Although some safety concerns have been raised in the use of MRI for foetal imaging, surveys of children scanned with MRI in utero have found no adverse outcomes later in life from this exposure. MRI examinations are usually only conducted in the second trimester. Most MRI units used to conduct foetal MRI are 1.5 Tesla (T).

The majority of studies included for assessment in this report were diagnostic accuracy studies that compared a diagnosis with ultrasound (US) to a diagnosis with MRI. In most studies, these results were compared to the reference standard of either postnatal clinical follow-up or post-mortem confirmation of diagnosis.

Studies included in this report described a number of diverse outcomes including: the number of discordant diagnoses between ultrasound and MRI; the number of discordant diagnoses between MRI and postnatal clinical follow-up or post-mortem results; additional information gained from MRI which resulted in changes to counselling and clinical management of the pregnancy; and the sensitivity and specificity of MRI compared to ultrasound. The majority of studies reported on findings of only one type of foetal abnormality, whereas the studies which scanned foetuses for all abnormalities, MRI was incorrect in a high number of diagnoses (39%). The diverse nature of abnormalities was considered to be the main factor in misdiagnosis by MRI, however studies such as this are more likely to reflect the situation encountered in obstetric clinical practice. In addition, it was reported that the discordant rate between US and MRI was reported to be greatly reduced (6.2%) when women underwent a confirmatory US, prior to MRI and conducted by the same institution where the MRI was to be conducted. Generally studies with low numbers of enrolled women reported larger discrepancies between the diagnosis with US and MRI, which may be a reflection of the need for extensive clinical expertise being required for the diagnosis of foetal abnormalities.

No studies included in this report described any adverse events that occurred as a result of conducting an MRI examination on a foetus, either to the foetus or the mother. Although no studies reported on the termination of pregnancies based on a false positive diagnosis obtained with MRI, a small number of studies reported on the misdiagnosis of foetal abnormalities by MRI. Of these, the largest number of misdiagnoses was described by Limperopoulos et al. Of 19 foetuses diagnosed with vermicul hypoplasia with prenatal MRI, six were confirmed as normal with postnatal MRI, a false positive rate of 32 per cent. None of these pregnancies were terminated, however the over diagnosis of vermian hypoplasia may have led to the unnecessary terminations.

In conclusion, MRI appears to be a useful adjunctive tool, in combination with ultrasound, for the diagnosis of some foetal abnormalities. Ultrasound remains the gold standard in the screening of pregnant women. In cases of equivocal ultrasound diagnosis, MRI may provide additional information which may improve prenatal parental counselling, alter the clinical management of the pregnancy and improve postnatal therapeutic planning. A confirmatory ultrasound in addition to the referral ultrasound, conducted by the same institution where the MRI is to be conducted, may be beneficial. MRI scans for foetal abnormalities should only be conducted in tertiary centres where parents may access the appropriate level of counselling.

Written by Linda Mundy, AHTA
Ultrasound for bone mineral density

Quantitative ultrasound (QUS) can be used to measure several parameters of bone structure, such as surrogate bone mineral density. Additionally, it may also provide information on bone microstructure. It is generally agreed that QUS does not directly assess bone mineral density (BMD) but rather the combination of bone structure with bone density gives QUS values that are strongly correlated with BMD, and thus, importantly, fracture risk.

HOW IT WORKS

Ultrasound is a mechanical wave and, as such, is affected by the mechanical properties of the substrates it passes through. QUS uses transmission of ultrasound through the assessed bone, in contrast to other ultrasound applications, such as foetal ultrasound, which uses pulse-echo methods.

QUS offers many advantages over conventional measures to assess bone health, including being safe, radiation free, portable, and inexpensive when compared to the gold standard, DXA. Additionally, as QUS is affected by more than just bone density, it may give more information about bone health than DXA, such as the structure of the target bone.

THE EVIDENCE

In a longitudinal study on 14,824 men and women who were followed for a mean period of 2 years, the ability of calcaneum broadband ultrasound attenuation to quantitate the risk of fracture was assessed. Those with the lowest 10% BUA values had a relative risk of 4.44 for fracture over a 2-year period compared to the subjects with the highest 30% of BUA values. A one-SD drop in BUA paralleled an increased relative risk of fracture of 1.95. Given all the advantages of QUS, this value compares favourably with the relative risk of 2.6 associated with a one-SD fall in a DXA based study. This study counted all fractures, not just specific osteoporotic fractures. Despite this, the relative risk of a hip fracture was 2.2 for a one-SD fall in BUA. There were differences in the relative risk of fracture for men and women, however this was accounted for by the differences in BUA between the sexes. This major study demonstrated that QUS could be used in both men and women to assess the risk of fracture.

A 10 year prospective study involving 3,883 women investigated the ability of DXA and QUS to identify women who are at an increased risk of fracture. DXA was performed on the neck and spine, and QUS was performed on the calcaneus. When considering all fractures suffered by the women, all techniques performed similarly, with a drop of one-SD in the measured values conferring a similar risk of fracture. The hazard ratio (HR) for any fracture per one-SD reduction in spine BMD was 1.61 and the neck of the femur was 1.54. The area under the curve (AUC) for a ROC analysis showed spine and femoral neck BMD to be significant predictors for all incident fractures (p <0.001). The HR for a one-SD reduction in BUA was 1.53 and 1.44 when adjusted for neck BMD.

FUTURE STEPS

There is a substantial body of literature published on this topic and given the potential benefits, HealthPACT have recommended that a Horizon Scanning report be conducted.

Written by Adrian Purins, AHTA

REFERENCES

Breast cancer diagnosis using ultrasound elasticity imaging

X-ray mammography is widely used in the diagnosis of breast cancer, and is safe and effective, many lesions found using this technique are of an indeterminate nature, and thus require biopsy for definitive status determination. Ultrasound (US) is used as an adjunct to X-ray mammography and has several useful advantages including: the ability to be used for women with dense breast tissue, guiding interventions such as biopsy, and in women for whom exposure to X-ray radiation is contraindicated.

**HOW IT WORKS**

Ultrasound elasticity imaging (USEI) is a modification of standard US to incorporate tissue compression and elasticity measurements to the scan result. Data are collected using the US device both before and after tissue compression. When using USEI and the breast tissue is subjected to compression, benign masses appear to remain the same size due to their definite boundaries, while malignant masses appear larger as the indefinite boundaries are enhanced visually under compression increasing the apparent size of the mass. Thus this technique allows the US device to distinguish between benign and malignant masses.

**THE EVIDENCE**

The ability of USEI to distinguish between benign and malignant lesions was reported in a prospective study of 101 consecutive patients referred for biopsy. The best parameters to distinguish benign lesions from malignant lesions were found to be area ratio or width ratio, that is, either the width or area of the lesion in the US image compared with the width or area of the lesion in the USEI image. The area and width ratios were not significantly different in their ability to distinguish benign or malignant lesions. Overall the sensitivity and specificity of USEI was 96% and 24%, respectively, for the area ratio; and 96% and 21%, respectively, for the width ratio. Distinguishing benign from malignant lesions was performed poorly when the assessors were in a busy clinical setting.

A study using continuous processing of US images to give USEI data showed that the method yielded a sensitivity and specificity of 85% and 88%, respectively. The patient group consisted of 86 consecutive patients who had a total of 100 solid breast tumours. Of these, 60 were benign and 40 were malignant by pathology.

USEI, US and X-ray mammography were compared in a 2007 study using fifty patients with either benign (n=25) or malignant (n=25) lesions. USEI was as sensitive (96%), and was substantially more specific (80% vs 68%) than US alone. The use of combined US and X-ray mammography greatly increased the sensitivity (ie the ability to correctly identify those who have the disease), but resulted in a much reduced specificity (ie the ability to correctly identify those who do not have the disease).

Most studies demonstrate that USEI gives an increase in specificity compared to US alone, at the expense of a reduction in sensitivity, although there is a wide disparity in the results of studies. The increase in specificity when using USEI is important due the fact that the main weakness of US is its false positive rate, leading to unnecessary biopsies. There appears to be progress from the earlier to the more recent studies which incorporate real time processing and display of the USEI data. In addition, different research groups have used different lesion parameters, cut offs and reference standards to establish the status of a lesion. Further improvements in USEI may be expected as the technology matures and standards and guidelines for which parameters and cut offs are used to determine whether a lesion is malignant or benign.

**FUTURE STEPS**

The field of USEI is rapidly evolving and shows promise in the deliverance of patient and economic benefits, however, the reduced sensitivity of USEI is of concern. The loss of sensitivity may be addressed by combining both mammography and USEI. In addition, this technology is diffusing rapidly with some centres in Australia currently utilising this technology. Therefore HealthPACT have recommended that this technology be monitored for further information in 12-months time.

Written by Adrian Purins, AHTA
Sleeve Gastrectomy as a single stage bariatric procedure: Executive Summary

Various strategies exist for the treatment of obesity: dietary changes, behavioural therapy and pharmacological interventions are widely utilised by clinicians and even patient’s themselves as a means of controlling obesity. The basic principle of weight loss is relatively straightforward, reduce food consumption and increase physical activity. However, medical studies have shown that attaining weight loss and maintaining it is not simple feat. Only ~25% of patients have successfully maintained long-term weight loss after undergoing caloric-restriction programs. Extreme forms of obesity (≥40 BMI) have been shown to respond poorly to dietary, behavioural and pharmacological treatment, with relapse rates of 90%. At the time of writing, bariatric surgery is the only proven technique capable of inducing long-term sustained weight loss in morbidly obese patients.

Recently, there has been substantial interest in a relatively new bariatric procedure, sleeve gastrectomy (SG). SG is essentially partial gastrectomy, where a majority of the stomach is resected to reduce stomach size. This should presumably result in reduced appetite and therefore decrease caloric intake. Previously, SG has been utilised as the first-stage procedure prior to biliopancreatic diversion gastric bypass. Extreme forms of obesity have been shown to respond poorly to dietary, behavioural and pharmacological treatment, with relapse rates of 90%. At the time of writing, bariatric surgery is the only proven technique capable of inducing long-term sustained weight loss in morbidly obese patients.

that SG may be capable of achieving substantial weight loss, therefore garnering considerable interest as a potential single-stage bariatric procedure.

Randomised clinical trials and comparative studies retrieved for discussion in this report have demonstrated that SG is capable of inducing substantial weight loss. Both of the included randomised trials revealed that SG results in significantly greater %EWL compared to lap-band surgery. However, the results of comparative studies were mixed. Two studies highlighted that Roux-en-Y gastric bypass (RYGBP) and duodenal switch achieved significantly higher %EWL compared to SG. Meanwhile, Vidal et al stated that weight loss attained by SG and RYGBP patients were similar. Despite these discrepancies, it is clear that SG is capable of achieving commendable weight loss (although significantly lower compared to RYGBP and duodenal switch) and there is strong evidence that SG is more effective than lap-band surgery.

Investigators have postulated that SG is not merely a restrictive procedure, but may have hormonal effects as well. This is due to the fact that during SG, the gastric fundus and the greater curvature (both key sites of ghrelin production) are completely resected, resulting in significantly decreased plasma ghrelin levels. This significant reduction in ghrelin could have contributed to the weight loss achieved by reducing the appetite of the patient, and may explain the relatively superior outcomes of SG patients compared to lap-band patients. The observed reduction of the feeling of hunger by Himpens et al in 75% of SG patients may be attributable to decreases in plasma ghrelin levels.

REFERENCES


(Continued on Page 7)
Sleeve Gastrectomy as a single stage bariatric procedure: Executive Summary

(Continued from Page 6)

Randomised trials demonstrated that SG has comparable and perhaps lower complication rates relative to lap-band\(^5,6\). However, it is important to note that one study reported more severe complications after SG despite attaining lower overall complication rates\(^6\). Relative to RYGBP and intragastric balloon implantation, SG appears to be significantly safer\(^8,10\).

Despite the encouraging results from the retrieved studies, the long-term safety and effectiveness of this procedure has not been investigated thoroughly. The significantly higher %EWL achieved compared to lap-band should be viewed in context of the fact that SG is substantially more invasive and is not reversible. Nevertheless, SG appears to have substantial potential as a single-stage bariatric procedure. Further studies with larger patient cohorts and long-term data are required before the efficacy of SG relative to established bariatric procedure can be determined.

Written by Irving Lee, ASERNIP-S

Other New and Emerging Technologies

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

- Skin biopsy diagnosis of peripheral neuropathy
- Boron neutron capture therapy for cancer treatment
- Ovarian cancer symptom index
- Smartinhaler\(^{TM}\) for asthma medication compliance


- Cryoplasty utilising the PolarCath peripheral dilation system
- Intralase femtosecond laser
- ProACT therapy for male stress urinary incontinence
- TandemHeart percutaneous ventricular assist device

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

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.

---

Editor: Linda Mundy
Design: Lashan Clifton
Writers/Information Specialists: Irving Lee, Linda Mundy, Luis Zamora, Adrian Purins, Janet Hiller
Contact: Adelaide Health Technology Assessment (AHTA) Discipline of Public Health, Mail Drop 511 The University of Adelaide Adelaide, South Australia 5005 Australia
email: ahta@adelaide.edu.au Telephone: +61 8 8303 4617 Fax: +61 8 8223 4075
www.health.adelaide.edu.au/publichealth/research/AHTA.html

---

WE VALUE YOUR FEEDBACK!

Please forward Newsletter feedback to:

Lashan Clifton
Ph: (08) 8303 4617
Email: lashan.clifton@adelaide.edu.au

Contact us with medical or surgical technologies, procedures, or health programs that are new or emerging in Australia.

Please forward to: Linda Mundy
Ph: (08) 8303 6256
Email: linda.mundy@adelaide.edu.au