JANURARY 2006

Technology Review

ELECTRO IMPEDANCE MAMMOGRAPHY (MEIK)

HEALTH TECHNOLOGY

Author
DR SHEAMINI SIVASAMPU
PRINCIPAL ASSISTANT DIRECTOR
HEALTH TECHNOLOGY ASSESSMENT UNIT
MEDICAL DEVELOPMENT DIVISON
MINISTRY OF HEALTH MALAYSIA

Reviewed and edited by
DATIN DR RUGAYAH BAKRI
DEPUTY DIRECTOR
HEALTH TECHNOLOGY ASSESSMENT UNIT
MEDICAL DEVELOPMENT DIVISON
MINISTRY OF HEALTH MALAYSIA

1. BACKGROUND

The Engineering Division, Ministry of Health, has requested the Health Technology Assessment Unit to carry out a technology review on the safety and effectiveness of Electro – Impedance Mammography (MEIK) as a screening tool for breast cancer.

2. INTRODUCTION

Breast cancer is a second leading cause of cancer deaths in women today (after lung cancer) in many parts of the world (Cancer Statistics 2004). Breast cancer is presently detected by palpation (clinical and self), by mammography and by adjunct imaging methods such as ultrasound and magnetic resonance imaging (Hope & Iles 2004). Currently, no single modality has high sensitivity and specificity for the diagnosis of breast cancer; most of the well established breast screening methods have high sensitivity but suffer from poor specificity.

X-ray mammography, which is the accepted gold standard for breast cancer screening, provides high sensitivity but has a high rate of false positives. When suspicious lesions are detected, biopsies are performed to determine whether the lesion is malignant (Hope & Iles 2004).

Therefore, new imaging techniques are being developed for earlier detection of breast cancer which are more accurate and less invasive in order to eliminate unnecessary biopsies (National Cancer Institute 2002).

From as early as 1926, researchers have been studying the electrical properties of breast tumour (Fricke & Morse 1926). Different types of tissue have different electrical impedance levels (electrical impedance is a measurement of how fast electricity travels through a given material). Some types of tissue have high impedance, while others have low impedance. Breast tissue that is cancerous has much lower electrical impedance (conducts electricity much better) than normal breast tissue, therefore, breast tumour may appear as bright spots on the computer screen (Demidenko et al 2005).

Available techniques using electrical impedance measurement methods

(i) *Electrical impedance scanning (EIS)* produces an impedance map of an object based upon the spatial electrical characteristics throughout the volume of the object. With this device, a probe that comprises of electrodes is paced over the breast and small amount of current is injected through another electrode placed on the palm of the patient. The electrical current travels through the body to a location where it is easily transmitted out. The magnitude and phase of the current is measured one electrode at a time and all electrodes are scanned sequentially. Using the distribution of electric currents in this electrode array, a conductivity map is reconstructed by a computer (Nalcioglu 2006). The T-Scan

2000 is the only commercially available system using the technique of electrical impedance scanning in the detection of breast cancer.

(ii) *Electrical impedance tomography (EIT)* was developed as an imaging technique in the 1980s to reconstruct the conductivity distribution inside a conducting volume. In this method, a current distribution is generated inside the object by injection or induction and peripheral voltage measurements are acquired. This device collects multi-slice tomographic impedance images of healthy and cancerous breasts. Two remote electrodes are placed on the patient's extremities for current injection and voltage reference. This allowed an assumption of spherical equipotential surfaces near electrode array to be used. Filtered back-projection along the equipotential surfaces was used for the fast three dimensional image reconstruction (Nalcioglu 2006). The two devices that use the principle of EIT are Electrical Impedance Mammography (MEIK) and Centillion.

3. TECHNICAL FEATURES

(i) MEIK
Is a hand held device consisting of a compact array of 256 electrodes is pressed gently onto the breast to be examined. A clip containing two reference electrodes is attached to one wrist. Small electrical pulses (0.5 mA, 50 kHz) are passed through the breast tissue to initiate the procedure.

A microprocessor selects one of the 256 electrodes to be the active electrode while the remaining 255 electrodes are measured for potential voltage drop. This procedure continues for each electrode until 65,280 voltage measurements are taken within 20 seconds. The detection device is connected to a medical-grade PC port during the procedure and the data is reconstructed by software into direct-to-digital tomography conductivity images of the breast. Seven tomography slices are created within 40 seconds at depths of 0.4 cm to 4.6 cm to detect and isolate tumours. The screening system consists of a portable PC, Portable EICM, a chair for examination and a small table for PC. A room or protected area of approximately 10 to 15 square metres with an access to electricity for the PC would be sufficient for the imaging to be carried out. No materials like gel or ECG spray are required (Bio Impedance (M) Sdn. Bhd.).

(ii) Centillion
This device has physical and technical features similar to MEIK (TC International).

(iii) T-Scan 2000
The T-Scan 2000 is similar in size and appearance to an ultrasound machine. There is a small cart mounted unit with monitor and keyboard. The patient holds a metallic wand that is similar in size and appearance to a "joy stick" on many computer games. One to two and half volts (1.0 to 2.5V) of compatible alternating

electrical current is generated by the system and conducted through the wand held by the patient. When the scanning probe is placed against the breast the electrical circuit is completed. Gel is used as an agent to improve conductivity between skin of the breast and scanning probe.

The scanning probe uses 256 sensors of high resolution mode and 64 sensors in normal resolution mode. The scanning probe is moved over the breast and its many sensors measure current signal at skin level. Images of the electrical impedance profile are digitally processed by the system's computer and produced in real time and appear as a 256 level gray scale format. The images are recorded into 9 sectors on a 3x3 sector matrix electrical impedance map of the breast. Impedance objects are defined as spots or regions that are brighter (or occasionally darker) than the surrounding sector image. The only white object that would appear in T-Scan examination of normal breast is the nipple (Imaginis).

4. OBJECTIVE

To assess the effectiveness, safety and cost effectiveness of Electro – Impedance Mammography (MEIK) in the screening of breast cancer.

5. METHODOLOGY

Retrieval of evidence-
Electronic searches of several databases namely Cochrane Systematic Review, DARE, NHS EED, HTA, MEDLINE, NCCAM and even internet search engine like Google were carried out. There were no limits applied when performing the search. The key words used singly or in combination during the search were "electro impedance"; "breast"; "electro impedance tomography"; "electro impedance scanning"; "MEIK", "Centillion"; "T-Scan 2000", "dielectric properties", "breast cancer screening"; "safety"; "efficacy"; "effectiveness" and "cost effectiveness".

6. RESULT AND DISCUSSION

6.1 SAFETY

(i) MEIK
No evidence was found with regards to the safety of this device.

(ii) Centillion
No evidence was found with regards to the safety of this device.

(iii) T Scan 2000

A cross-sectional study found that 1103 patients who underwent electrical impedance scanning using T scan 2000 were satisfied with the comfort, speed and reporting of EIS screening (Stojadinovic et al 2005).

T- Scan 2000 has not been studied on patients with implanted electronic devices, such as pacemakers. Therefore, T-Scan 2000 is not recommended for such patients. Similarly the safety of the T-scan 2000 has not been established in pregnancy (summary of safety and effectiveness data).

6.2 EFFECTIVENESS

(i) MEIK
This device has been approved by the Russian Ministry of Health since July 2003 as an investigative device, as an adjunct to ultrasound and x-ray mammography (Bio Impedance (M) Sdn. Bhd.).

The only evidence available on MEIK is an unpublished literature which appears to be a cross-sectional study carried out in a hospital in Yaroslavl, Russia. However, this study was found to be of low level evidence (Report on conducting of the clinical tests of diagnostic instruments for Electro Impedance Mammography “MEIK”).

A cross-sectional study has been conducted on women who underwent breast cancer screening in the National Cancer Society Malaysia. Period of data collection was from 16 December 2004 until 10 January 2005. This study used MEIK as an adjunct to ultrasound and X-ray mammography. The findings of the study have yet to be analysed and published (personal communication).

(ii) Centillion
Centillion is another imaging device using the principles of electrical impedance tomography. However, there was no published evidence with regards to this device. We have contacted the manufacturer of this device in the United States (US) and have been informed that this device is in the investigational and clinical trials stage in the US. The intended use of this device is as an adjunct to existing X-ray mammography. The manufacture, however, was not at liberty to share the details of the ongoing clinical trials being conducted (personal communication through e mail).

(iii) T- Scan 2000
The T-Scan 2000, also known as the T-Scan is an example of an electrical impedance scanning device. This device was granted FDA pre-market approval on April 19, 1999. The intended use of this device is as an adjunct to mammography in patients who have equivocal mammographic findings within ACR BI-RADS*TM* categories 3 or 4. This device is not approved as a screening device for breast cancer, and is not used when mammography or other findings

clearly indicate the need for biopsy (United States Food and Drug Administration, National Cancer Institute, USA 2002)

A recent cross-sectional study showed that electrical impedance scanning sensitivity and specificity in women younger than 40 years was 50% and 90% respectively. This study, however, demonstrated that false positives were increased in postmenopausal women and those taking hormones who underwent electrical impedance scanning (Stojadinovic et al 2005).

Hope & Iles (2004) carried out a review on TS 2000. This review demonstrated that when used in conjunction with mammography, the TS Scan 2000 increased the sensitivity and specificity of breast cancer detection. However, this review went on to conclude that evidence is still lacking with regards to electrical impedance scanning in areas to show the differences in electrical properties of various breast pathologies, frequency response for both normal and pathological tissue breast tissue, post processing the output maps to discriminate between benign and normal breast tissue and three dimensional reconstruction algorithms (Hope and Iles, 2004, Nalcioglu 2005)

There are no prospective clinical studies demonstrating the clinical utility of electrical impedance scanning (EIS) in distinguishing benign from malignant breast lesions, either in place of, or as an adjunct to mammography or magnetic resonance imaging. Therefore, both Aetna and Health Link consider that electrical impedance scanning of the breast to be experimental and investigational device (Aetna Policy Bulletin-0386, Health Link-00044).

7. COST IMPLICATIONS

There are no studies available on the cost implications of electrical impedance in breast cancer detection.

8. CONCLUSION

There is no evidence on the safety, effectiveness and cost implications with regards to MEIK and Centillion in breast cancer detection.

However, there is some evidence on the effectiveness and safety for T-Scan 2000 as an adjunct to X-ray mammography in the detection of breast cancer.

REFERENCES

Aetna – Clinical Policy Bulletin. Breast Transillumination and Electrical Impedance Scanning. http://www.aetna.com/cpb/data/CPBA0386.html. Accessed 14/12/2005

Breast Cancer, Mammography. http://www.emedicine.com/radio/topic793.htm. Accessed 14/12/2005
EIS Breast Imaging Research at Dartmouth College. http://wwwnlm.dartmouth. edu/biomedprg/EIS/index.html. Accessed: 14/12/2005

Fricke H, Morse S. the electrical properities of tumors of the breast. J Cancer res 1926, 16:310-376

Health Link. Electrical Impedance Scanning for Breast. MED.00044. Accessed 12/12/2005 –reviewed 14/7/2005
Jernal A, Tiwari RC, Murray T, et al (2004). Cancer Statistics, 2004. CA Cancer J Clin. Jan (1): 8-29

National Cancer Institute Fact Sheet (2002). Improving Methods for Breast Cancer Detection and Diagnosis. http://www.cancer.gov. Accessed 14/12/2005

Nalcioglu O (2006). Magnetic Resonance Electrical Impedance Tomography. A Novel Technique for Cancer Imaging. Business Briefing: Future Directions in Imaging. http://www.touchbriefing.com

On conducting of the clinical tests of diagnostic instrument for electro impedance mammography “MEIK”. Unpublished report.

Stojadinovic A, Nissan A, Gallimidi Z, Lenington S, Logan W, Zuley M, Yeshaya A, Shimonov M, Melloul m, Fields s, Allweis T, Ginor R, Gur D, Shriver CD (2005). Electrical impedance scanning for the early detection of breast cancer in young women: preliminary results of a multicenter prospective clinical trial. J Clin Oncol. April 20; 23 (12): 1703-15

United States Food and Drug Administration. Summary of Effectiveness for Trans Scan T-S 2000. http://www.fda.gov/cdrh/pdf/p970033.html. Accessed 12/12/ 2005