

Clinical Trial of Sentinel Node Biopsy using MAGnetic Nanoparticles: A Multicentre Phase II/III clinical trial to compare sentinel node biopsy using magnetic nanoparticles vs the combined technique.

Mr. Michael Douek presented this very interesting and important trial to the Independent Cancer Patient Voices at the House of Commons on March 4th 2011. The aim of this multicentre phase III trial is to evaluate the standard sentinel node biopsies against a new magnetic method.

Superparamagnetic contrast agents (SPIOs) are injected near the tumour. SPIOs are clinically proven to be non-toxic having been used for almost 20 years as contrast agents for MRI when injected intra-venously. A hand-held magnetic scanner (called SentiMag) is then used to find out if the magnetic particles have spread to any of the draining lymph-nodes indicating whether or how far the cancer has spread.

Technique/Advantage	SentiMag	Gamma Probe
Avoids Radiation	✓	✗
Surgeon Controlled	✓	✗
Established Working Practice	✓	✓
Inexpensive Consumables	✓	✗
Spatial Imaging	✓ (MRI - high res)	✓ (Scintigraphy - low res)

Sentinel lymph node biopsy today involves a blue dye, radioactive tracer and a gamma-ray detector. While effective, this method comes with significant problems. The method is limited by the supply of the radioactive tracer. It decays so quickly that it must be supplied to hospital nuclear medicine departments every week, and is made in just a handful of nuclear reactors worldwide. The handling of radioactive materials is subject to

stringent regulations, requiring special staff training and segregation of the waste from the operating theatre. The costs in providing and handling the radioactive materials are high.

Surgeons find that the blue dye can make the details of the breast and lymphatic tissue difficult to see and can interfere with the surgery.

In contrast to the radioactive tracer, a typical magnetic tracer has a shelf life of several years. There are no staff safety issues, and therefore no regulatory burden. It is also much cheaper for the hospital than the radioactive tracer, and is therefore accessible to all.

ICPV welcomed this new clinical trial. Quality of life would be vastly improved without the need for radical axillary dissection with all the concomitant problems of lymphoedema, sensation loss and restricted movement. If the pre-operative imaging for the detection of involved nodes is made easier and cheaper it would mean a big step forward in the detection of involved axillary nodes in many more women with breast cancer.