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Association of Breast Surgery Guidelines Use of Blue dye for SLNB 2009

Increasingly sentinel lymph node biopsy (SLNB) is the preferred method for staging the axilla in early breast cancer (NICE Guidelines 2009). In the UK the SLN is successfully localized in 99% of patients using a combined technique of radioactive (TcM99m) labeled nanocolloid and 2mls of diluted Patent V blue dye injected into the breast (NEW START Programme). SLNB using the dual localisation protocol is now being used for other tumours, notably melanoma, penile, testicular, cervical and head and neck cancers.

Patent V blue, a colorant used in textiles and food (E131), has also been used in lymphangiography since the 1960s. It is associated with allergic reactions ranging from mild urticarial rash (grade 1) to severe anaphylaxis requiring inotropic support (grade 3). No mortality has been reported. NEW START and ALMANAC, the largest UK SLNB datasets, recently demonstrated a 1% allergy rate in nearly 6000 procedures (1). The majority of these reactions were grade 1 but non-fatal cardio-respiratory arrest has been reported elsewhere (2).

Other blue dyes used for SLNB are methylene blue, and isosulphan blue (an isomer of Patent V), popular in the USA. Isosulphan blue reaction rates are about 1.4%. Methylene blue, used less commonly because of concerns about lymphatic uptake and fat necrosis at the injection site seems to have less reactive potential but this may represent lower numbers combined with reporting bias.

In the UK we diagnose over 44000 new breast cancers per annum of which 25-30000 may be suitable for SLNB. A 1% reaction rate would equate to 250-300 adverse events per annum for breast procedures, and with the increasing use of SLNB for

other tumour sites we are likely to see more reactions; every effort must be taken to minimise patient risk.

Recommendations:

- Patients must be informed of the use of blue dye and its allergic potential as part of the consent process, and the risk documented on the consent form
- For patients with a history of previous severe allergies, especially to food colourants, or those who carry an EpiPen ®, consider pre-operative skin patch testing. If the SLN is adequately localised with isotope (a scintiscan is helpful) blue dye may not be required, though this has the potential to reduce localisation success.
- Any reaction must be reported to the Committee of Safety in Medicines (Yellow card scheme).

1. *San Antonio Breast Cancer Symposium 2008 – paper in press*

2. *Wohrl S, Focke M, Hinterhuber G, Stingl G, Binder M. Near-fatal anaphylaxis to patent blue V. Br J Dermatol 2004; 150: 1037-8.*