

Sentinel Lymph Node Biopsy for Cutaneous Melanoma — a new procedure for the BADS Directory?

ANEETA SINHA, JACQUELINE E REES-LEE, DAVID J SANDERS & CHRISTOPHER STONE

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Abstract:

Sentinel lymph node biopsy (SLNB) is a surgical technique for staging regional node fields in patients with cancers that have a propensity to metastasise to lymph nodes. We report our experience of SLNB for cutaneous melanoma in the first 150 consecutive patients treated in our plastic surgery unit. SLNB was performed at the time of wide local excision (WLE) of the original melanoma scar and the day surgery pathway for this process is described. Our patients were aged between 16 and 85 years with an average age of 56 years. Sixty-two of the 150 patients (41%) were successfully managed as day cases. Day surgery rates for successive cohorts of 50 patients increased progressively (34%, 40% and 50% respectively) although the day surgery rate for patients with lower limb WLE sites (20%) was much lower than for patients with primaries located elsewhere on the body. The majority of patients (142) had the procedure performed under general anaesthesia. We have demonstrated that SLNB for cutaneous melanoma, in combination with wide-local excision of the primary biopsy site, can be performed as a day case procedure in up to half our patients. Success relies on a multidisciplinary team approach from the outset, with education of staff and patients and timely coordination of all the required services.

Introduction

Sentinel lymph node biopsy (SLNB) is a surgical technique for staging regional node fields in patients with cancers that have a propensity to metastasise to lymph nodes¹. Most experience has been obtained from patients with melanoma and breast cancer and it has become a standard of care for the staging of clinically node-negative melanomas and breast cancers^{1,2}. SLNB has also been described for other types of carcinoma, such as thyroid, gastrointestinal, oropharyngeal, vulval and penile carcinomas^{3,4}.

The technique involves the injection of an in vivo tracer to identify the first, or 'sentinel', lymph node or nodes that receive lymph draining directly from a primary tumour site and to direct their subsequent surgical removal for careful and detailed histological examination¹. If the sentinel node is free from metastatic disease, it can be inferred with a high degree of accuracy that the remaining nodes in the field are uninvolved and that further surgery is not required. Histological confirmation of malignant spread to the sentinel node would normally be followed by further surgery to clear the remaining regional nodes, potentially in combination with adjuvant therapy. The consensus from two international congresses on the sentinel node is that the best approach to SLNB is to employ preoperative lymphoscintigraphy (with a gamma emitting radioisotope), vital dye injection just before surgery and a hand-held gamma-detection probe during the surgery itself. Maximum accuracy is achieved by combining these three techniques in each patient¹.

SLNB has minimal associated patient morbidity and provides accurate prognostic information¹ which is of critical importance to the recruitment of patients to modern adjuvant therapy trials⁵. When the sentinel node is negative, patients are reassured, and when it is positive, the completion lymphadenectomy can often be undertaken with less surgical morbidity than when macroscopic disease is present.

SLNB is part of the current American Joint Committee on Cancer (AJCC) staging classification for the TMN classification of melanoma⁶ and the 2002 UK guidelines for the management of cutaneous melanoma, endorsed by the British Association of Plastic Surgeons, recognise the role of SLNB for the staging of intermediate thickness melanomas in specialist centres⁷. At the time of commencement of our service in January 2003, the main benefit of SLNB was its ability to provide accurate and minimally invasive tumour staging^{1,2}. However, a large prospective randomised controlled trial has now demonstrated that, in patients with intermediate thickness melanoma, there is a clear prognostic and survival advantage from SLNB combined, if the node is positive, with early completion lymphadenectomy⁸.

Authors' Addresses

ANEETA SINHA Senior House Officer in Anaesthesia
 JACQUELINE E REES-LEE Senior House Officer in Plastics & Reconstructive Surgery
 DAVID J SANDERS House Officer in General Surgery
 CHRISTOPHER STONE Consultant in Plastics & Reconstructive Surgery,
 Royal Devon & Exeter Hospital, NHS Trust, Barrack Road, Exeter, EX2 5DW
 CORRESPONDENCE TO: A Sinha, Department of Anaesthesia,
 Poole Hospital NHS Foundation Trust, Longfleet Road, Poole, Dorset, BH15 2JB

Because SLNB is a relatively non-invasive addition to the surgical management of melanoma, we set out to determine what proportion of patients could realistically undergo this procedure on a day case basis.

Patients and methods

The findings from the first 150 consecutive patients undergoing SLNB for cutaneous melanoma in our unit are presented. The initial 100 patients were aged between 16 to 85 years but an upper age limit around 65 years was introduced for subsequent patients. This change was made because evidence from longterm multicentre follow up has failed to demonstrate any survival benefit from elective lymph node dissection in patients over the age of 60⁹.

Patients are considered for SLNB if they have a primary cutaneous melanoma with a Breslow thickness greater than 1 mm, no palpable nodal disease and are judged fit enough to undergo a completion lymphadenectomy if their sentinel lymph node biopsy is positive (i.e. is shown to contain melanoma cells on histological examination). Wide local excision (WLE) of the original melanoma scar is standard practice in melanoma management⁷ and we perform the SLNB at the time of this re-excision. The defect resulting from the WLE may require reconstruction with a local flap or split skin graft and for a lower limb site this usually precludes day surgery, due to the need for postoperative bed rest to elevate and immobilise the grafted area.

The diagnosis of melanoma and procedures of WLE and SLNB are discussed in clinic by either the consultant or registrar of the melanoma specialist plastic surgical team. Patients also receive support from a skin cancer clinical nurse specialist from the time of their initial diagnosis of melanoma. The majority of our patients are fully preassessed ten to fourteen days before admission by a nurse practitioner, specialised in the field of plastic surgery, who confirms that, where feasible, each patient is assigned to the appropriate day surgery or inpatient treatment pathway. It is not always possible to determine prior to surgery whether patients will require a drain or a local flap or split skin graft (SSG) to close the WLE site and therefore a definitive assignment to day case or inpatient surgery may not be feasible. Whenever practicable, staging CT scans are scheduled on the same day as preoperative assessment to reduce the number of visits to hospital.

The majority of patients are admitted to the specialist plastic surgical ward on the morning of surgery, where they are seen by the anaesthetist, normally a consultant with an interest in day surgery. The consultant plastic surgeon and skin cancer clinical nurse specialist also review the patients on admission. Later that morning, patients attend the nuclear medicine department for their preoperative lymphoscintigraphy. These appointments are prebooked to complement the timing of surgery for an afternoon list. A superintendent radiographer, trained and accredited in injecting the radioisotope, performs the lymphoscintigraphy. Four, ten megabecquerel (MBq) doses of technetium 99m

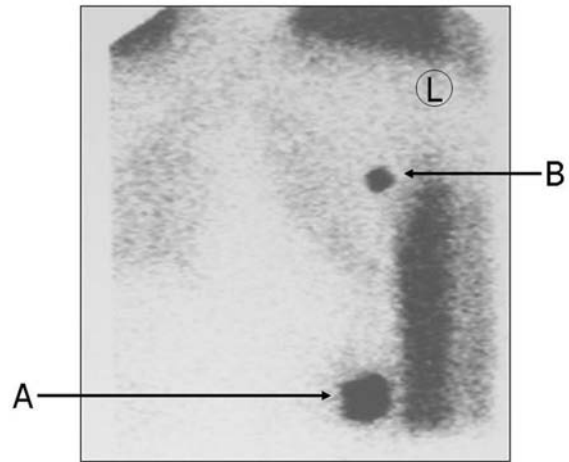


Figure 1 Lymphoscintigram showing radioactive tracer injected at the excision site of a left flank primary melanoma (A) and localising to a sentinel node (B) in the ipsilateral axilla. The dark background surrounding the patient represents gamma rays emitted from the cobalt 60 gamma source panel placed under the patient to produce an outline of the body in order to assist location of the sentinel node.

(^{99m}Tc) nanocolloid are injected equally around the middle third of the original melanoma excision scar, giving a total dose of 40 MBq with a half life of six hours¹⁰. Sequential lymphoscintigrams are acquired with a gamma camera, immediately after injection of the ^{99m}Tc. The scan (Figure 1) is assessed by the radiographer who marks the patient's skin, identifying the 'hot spots' (which represent the sentinel lymph node or nodes) first showing radioactivity. The lymphoscintigraphy takes approximately 45 minutes to an hour to perform and patients then return to the ward wearing a yellow wrist band, to indicate that they have received a radioisotope. The lymphoscintigrams can be viewed on the hospital PACS system, but hard copies also accompany the patient to theatre.

The majority of excisions and biopsies are performed under general anaesthesia (GA) using a standard technique of induction with midazolam, fentanyl and propofol. The patient's airway is normally maintained with a laryngeal mask airway, an endotracheal tube being used only if specifically indicated. Anaesthesia is usually maintained with oxygen, nitrous oxide and isoflurane. Analgesia is provided by preoperative paracetamol and NSAIDs (unless contraindicated), infiltration of all operative sites prior to surgery with bupivacaine 0.5% with adrenaline 1:200,000 and regular postoperative paracetamol and NSAIDs plus tramadol, if required. In selected patients, we have successfully performed WLE and both groin and axillary SLNB under local anaesthesia alone, or in combination with sedation. Sedation is usually achieved with a combination of boluses of fentanyl (25–50 µg) and propofol (10–30 mg). Oxygen is administered via nasal cannulae during sedation.

The surgery is performed in the specialist plastic surgery theatre, rather than our day surgery unit. Intraoperatively, the sentinel node or nodes are identified from the preoperative lymphoscintigram, by an injection of patent blue dye into the melanoma scar immediately after induction of anaesthesia and by the intraoperative use of a hand-held gamma detection probe (Figure 2). Confirmation of a sentinel node is made by the combination of its high

level of radioactivity and blue staining conferred by the patent blue dye transported along the lymphatics draining the site of the original tumour.



Figure 2 Hand held gamma detection probe in use to confirm the incision for excision of a sentinel node in the right groin.

Residual radioactivity on the instruments and swabs requires these to be quarantined and isolated for twenty-four hours. This allows sufficient time for the radioactivity to decay to safe levels. Initial radiation levels in the excised tissues are higher, so the pots containing these samples must be stored in a lead-lined box for the 24 hour quarantine period. The advice given to patients is that they should avoid close contact with children or pregnant women for 24 hours.

Patients are transferred back to the plastic surgical ward from the post-anaesthetic recovery room. Their final discharge is nurse-led, based upon standard criteria and, for day cases, typically between 2–3 hours after return to the ward.

Results

The data presented cover the first 150 patients undergoing SLNB for intermediate thickness melanomas in Exeter between January 2003 and November 2005. These patients were aged between 16 and 85 years with an overall average age of 56 years. Because of the change in selection criteria, the average age of the first 100 patients was 60 years whereas it was only 48 years in the last 50 patients. Sixty-seven patients were female (45%) and 83 were male. Of the 150 cases, 142 were performed under general anaesthesia, five under local anaesthesia alone and three under local anaesthesia with sedation.

Sixty-two patients (41%) had the procedure performed as a day case while 88 were inpatients, of whom 14 (16%) were admitted one night preoperatively, most commonly due to their travelling distance to the hospital. A number of patients had preplanned postoperative admissions for social or surgical reasons, such as leg immobilisation following anticipated skin graft reconstruction of lower limb wide local excision sites, or for drainage of very large excision sites. In other patients, the management of the WLE site could only be determined at operation, so suitability for same day discharge had to be confirmed postoperatively.

There was a progressive increase in the day surgery rates achieved for successive cohorts of 50 patients, these being 34%, 40% and 50% respectively. Table 1 shows how the percentage day case rate varied with the age group of patients within each cohort. Table 2 illustrates the distribution of length of stay in hospital for the entire patient group. Overall, 121 patients (81%) spent less than two nights in hospital.

Table 1 Percentage day case rate stratified according to age group within each cohort of patients. The final cohort excluded patients aged over 70 years.

Cohort of patients	Day surgery rate according to age	
	70 years or less	Over 70 years
First 50 patients	15 / 35 (43%)	2 / 15 (13%)
Patients 51–100	16 / 32 (50%)	4 / 18 (22%)
Patients 101–150	25 / 50 (50%)	-

Table 2 Duration of hospital stay for the entire group of 150 patients undergoing wide-local excision and sentinel lymph node biopsy for melanoma

Duration of hospital stay	Number (%) of patients
Day surgery	62 (41.3%)
One night	59 (39.3%)
Two nights	12 (8%)
Three nights	3 (2%)
Four nights	7 (4.7%)
Five or more nights	7 (4.7%)

The commonest site for primary melanoma within this series was the trunk (40%) with the lower limb as the next most frequent location (27%). The day surgery rate for all patients with lower limb wide local excision sites was 20%, which was much lower than for patients with primaries located elsewhere on the body (Table 3). The proportion of lower limb melanomas in patients aged 70 years or under (24%) was not significantly different from that in those over 70 years (37%; $p = 0.15$).

Table 3 Anatomical distribution of primary melanoma sites and related day case rates for wide-local excision (WLE) and sentinel lymph node biopsy (SLNB)

Anatomical site of primary melanoma	Number (%) of patients	Number (%) of WLE & SLNB completed as day surgery
Head or neck	24 (16%)	11 (46%)
Arm	26 (17%)	13 (50%)
Trunk	60 (40%)	30 (50%)
Leg	40 (27%)	8 (20%)

The length of the surgical procedure varied from 30 to 90 minutes and depended upon several factors, including whether a skin graft was required for closure of the WLE site, whether the patient required repositioning on the operating table between the WLE and node biopsy and whether two surgeons were available to allow simultaneous WLE and node biopsy.

All patients received a follow-up out patient appointment with a skin cancer Clinical Nurse Specialist (CNS) within three weeks of their surgery. Approximately 20% of patients phoned the CNS between their SLNB and their clinic appointment, primarily for reassurance and to maintain contact, rather than for clinical complications. In those patients where the SLNB was positive for melanoma, completion lymphadenectomy was performed, as an inpatient procedure, within 2–4 weeks.

Discussion

SLNB serves to identify those patients with occult nodal metastases, thereby accurately targeting patients who, on the basis of proven occult nodal disease, might benefit from early nodal clearance, while sparing patients with histologically negative nodes the inevitable surgical morbidity of an unnecessary elective lymphadenectomy, as was widely advocated prior to the inception of the sentinel node technique⁴¹.

The findings of the Melanoma Sentinel Node Trials group, published in 2006, showed improved five-year survival (72% versus 52%) in SLNB positive patients undergoing immediate completion lymphadenectomy compared with patients managed by delayed lymphadenectomy for clinically detected nodal relapse⁸. This study has attracted some criticism on the basis of the comparison of patients who were sentinel node positive and received a completion lymphadenectomy with those requiring therapeutic lymphadenectomy for palpable disease. This comparison assumes that all patients with occult micrometastatic disease will progress to macroscopic nodal involvement⁴². While this hypothesis remains unproven, it should be noted that the percentage of sentinel node positive patients in the treatment group equated almost exactly to the percentage of patients in the control group who ultimately required a therapeutic lymph node dissection. Improving outcomes guidance from NICE has recommended that those UK units currently engaged in SLNB for melanoma should continue to collect data and publish their results, while those units that currently do not have expertise in the technique should await further outcome data⁴³.

Exeter is one of a limited number of centres in the UK currently offering SLNB to their melanoma patients and we have experience of over 250 cases performed since January 2003. There are few absolute exclusion criteria for SLNB and many patients with cutaneous melanoma are consequently suitable for the procedure. The potential therefore exists for a new service to expand rapidly, placing a strain on ward, theatre and financial resources. In line with recommendations for modernisation in the NHS and the number one 'High Impact Change' of treating day surgery as the normal pathway for planned surgery⁴⁴, we were keen from the outset to offer patients SLNB as a day case procedure. Maximising day case throughput of SLNB should help reduce the financial burden and inpatient workload placed upon centres offering SLNB. These issues are well described in a recent paper from the melanoma unit at St

George's Hospital, which examined both the feasibility of, and patient satisfaction with, SLNB performed as a day case procedure⁴⁵. Although this group did not report their overall day surgery rate for WLE and SLNB, the figure for total activity given in their discussion suggests that it would probably have been about 20% during the 18-month period analysed⁴⁵.

Compared with other day surgery undertaken at the Royal Devon & Exeter Hospital, the SLNB service we offer covers a much larger geographic area, including the whole of the Southwest peninsula. Despite this extended catchment area, we have demonstrated that it was possible to perform SLNB as a day case procedure in 41% of our patients. The results illustrate an increase in the day surgery rate for successive cohorts of 50 patients. A small improvement in day case rates occurred for both younger and older patients between the first and second cohorts. This can probably be attributed to our increasing experience and confidence in delivering this service as a day case procedure. The last cohort had no patients over the age of 70, as this age group was excluded due to evidence from long-term multicentre follow-up failing to demonstrate any survival benefit from elective lymph node dissection in patients over the age of 60⁹. The introduction of this age limit was responsible for the improvement in overall day surgery rate (from 40% to 50%) between the second and third cohorts of patients. This finding should not be misinterpreted to suggest that older patients should not be offered day surgery, because there is good evidence to support its success and benefits in the elderly⁴⁶. Our day case rates were lower for patients over the age of 70 due to both higher levels of co-morbidity and logistical reasons, such as greater reliance on hospital transport and lack of a competent adult to provide care after discharge. There was no significant difference in the proportion of leg primary sites between the younger and older age groups; another factor associated with lower day surgery rates.

We aimed to manage patients as day cases unless this option was excluded by medical or social conditions, but unlike many other typical day surgery procedures (e.g., hernia repair), the magnitude of this operation can, and not uncommonly does, vary on the day. Patients were advised at preassessment of their likely management, but were also told that they would probably need to be admitted if they required a drain or skin graft. Conversely, other patients in whom a SSG or drain was anticipated were advised that, if this was not required, they might be able to go home on the day of surgery. This uncertainty makes direct comparison with other elective day surgery difficult and limits the value of any analysis of outcome based on intention to treat as day surgery. We have for this reason adopted the pragmatic approach of presenting the day case rates actually achieved within various groups.

The admission of patients receiving skin grafting of a lower limb WLE site (required for postoperative immobilisation of the limb) explains the much lower day case rate (20%) for patients with lower limb primary excision sites. Unlike the St Georges melanoma unit, we did not exclude patients with head and neck primaries from day surgery. Our experience

has been that this group of patients do not pose any additional difficulties and we have achieved day surgery rates similar (46%) to those in patients with upper limb or trunk primary sites (50%). We would therefore encourage other groups planning to introduce day case SLNB to include patients with head and neck primaries from the outset.

The success of SLNB as a day case procedure relies on a multidisciplinary team approach and appropriate education of both staff and patients. Close cooperation between the surgical team, nuclear medicine and histopathology is necessary. Other key members of the multidisciplinary team include the specialist nurses – in preassessment, skin cancer and plastic surgery – and the anaesthetist. All staff involved should have a clear understanding of the patient pathway for SLNB and its suitability as a day case procedure. The team is also responsible for educating ward, theatre and recovery nurses. This is particularly important when, as in Exeter, the procedure is performed through a specialist plastic surgery ward, inpatient theatre and main recovery, rather than in a day surgery unit. The patient's expectation that they will have their SLNB as a day case procedure should begin in clinic and be reinforced at preassessment.

The timing of the preoperative lymphoscintigraphy is also important, both for successful SLNB and to enable these patients to be day cases. Adequate levels of the radioisotope need to be present to be detectable, both by preoperative lymphoscintigraphy and by the hand-held gamma probe during surgery². By performing the lymphoscintigram only a few hours before surgery, sufficient levels of isotope are present in the sentinel node for its identification without significant uptake occurring in the second echelon nodes. This, in turn, avoids the identification and retrieval of numerous 'non-sentinel' nodes, which would increase operative time and local wound morbidity (occasionally two 'sentinel' nodes are identified and, if this occurs, both are removed at SLNB and sent for histology. If either is positive we would proceed to lymphadenectomy). Thus, same day admission and discharge is possible by performing preoperative lymphoscintigraphy in the morning and WLE and node biopsy on an afternoon surgical list².

Our melanoma SLNB service accepts patients from a wide geographical area. Therefore, in appropriate patients, preassessment is conducted by telephone interview to avoid the need for additional patient journeys. Even when SLNB becomes more widely adopted it will still be performed in specialist centres, so travelling distance is likely to be an important issue when considering selection of potential patients for day surgery. The traditional view has been that patients undergoing day surgery should live within an hour's travelling time of the surgical unit. However, we have successfully managed patients who live up to two hours drive from Exeter as day cases. Once they reach home, provided patients can access their local DGH, any early anaesthetic or surgical complications, such as a wound haematoma or infection, can be managed locally in consultation with the SLNB centre. To date, no patients have actually required distant admission for an acute complication, although a few patients have been directed to their local practice nurse for

attention to the WLE wound. Patients with problems relating to the SLNB site (e.g., lymphocele) are brought back for review by the surgical team.

Our skin cancer clinical nurse specialist (CNS) plays a vital role in coordinating the post-discharge care of melanoma patients, and in providing both face to face and telephone support. Following their initial postoperative clinic visit at 2–3 weeks after SLNB, all patients are subsequently seen every three months at 'shared care' follow-up appointments, alternating between consultant and CNS skin cancer clinics.

The option of undertaking SLNB under local anaesthesia (LA) in suitable patients could have advantages. SLNB has previously been shown to be safely and adequately performed under LA with minimal discomfort to the patient⁴⁷. These authors performed axillary SLNB under LA in an outpatient setting in patients with breast cancer and found that sedation was unnecessary. SLNB of axilla and groin has also been performed using the technique of tumescent local anaesthesia, although sedation was necessary in 25% of patients⁴⁸. However, neither of these groups were carrying out simultaneous WLE of the original tumour site. Although we have successfully treated a few patients under local anaesthesia alone, or in combination with sedation, our experience is too limited to comment on its general suitability.

In conclusion, we believe that sentinel lymph node biopsy can be performed as a day case procedure in combination with wide-local excision of the primary biopsy site in many, if not the majority, of melanoma patients and it is our intention to increase the proportion of our patients undergoing SLNB in this way. With increasing evidence of the benefits of SLNB, the number of experienced UK centres offering SLNB is likely to grow, but some patients will still have to travel significant distances to access the service. As with all day surgery, the success of SLNB as a day case procedure relies on a multidisciplinary team approach from the outset, education of all the staff and patients involved and the availability and coordination of all the services required for the procedure. A flexible approach is required because, in a proportion of patients, the final suitability for same day discharge cannot be confirmed until the surgical management of the wide local excision site has been determined at operation.

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