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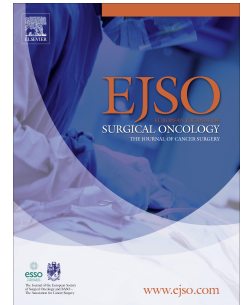


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Establishing axillary Sentinel Lymph Node Biopsy (SLNB) for early breast cancer in the United Kingdom: A survey of the national training program

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ABSTRACT

Introduction

The UK National training programme (NEWSTART) for SLNB in breast cancer was established in 2004, aimed at providing structured, standardised training with a focus on multidisciplinary team (MDT) delivery.

Methodology

A questionnaire was devised and after approval by the Association of Breast Surgeons (ABS) executive committee they were sent to all full members of the ABS.

Results

Most (97%) of breast surgeons are convinced by the evidence for SLNB as standard of care for early breast cancer. 64% use SLNB to stage clinically node negative patients, of whom 23% use it as a standalone procedure.

38% of surgeons were dissatisfied with the time it takes to complete the in house training, and 87% with the time it takes to complete the validation phase. Logistical and funding issues were the main problems cited.

The majority of surgeons (86%) use the recommended combined technique, with 47% continuing to use the dual localisation method. 14% use either blue dye or isotope alone, without scintiscan. Only 10% offer intra

operative diagnosis, of which the majority (6%) use touch imprint cytology. 31% included their results in their most recent surgical appraisal.

Conclusions

The majority of breast surgeons in the UK are convinced by the evidence for SLNB, and most use SLNB in their practice for staging. Reasons for not conducting SLNB are logistical rather than lack of belief in the procedure. The majority of respondents completed their training within the anticipated time line. The majority of centres do not perform intra-operative assessment.

FULL ARTICLE

BACKGROUND

Introduction

Sentinel node biopsy (SLNB) is now the recognised standard of care for axillary staging in patients with early breast cancer. There is level 1 evidence to support its staging accuracy as well as lower morbidity when compared to axillary lymph node dissection (ALND)¹⁻⁵.

The UK SLNB training program (NEW START), a collaborative project between the Department of Health, the University of Cardiff and the Royal College of Surgeons of England, was launched in October 2004. This unique national educational initiative aimed at providing structured, standardised training with a focus on multidisciplinary team (MDT) delivery. Patient safety was the primary aim and central audit and validation was integral to the program.

The training program was offered regionally and at a modest cost to breast teams. It was promoted through professional associations, the Royal College of Surgeons and government bodies. The target of the campaign was consultant and associate specialist surgeons, breast teams, hospital senior managers and cancer networks. The plan was to ensure a rapid, national coverage and uptake. The aim of the project was to train 80% of UK breast teams over a 4 year period. The targeted duration of completion of the program was 24 months per team.

The steering group anticipated the main barriers to delivering a uniform national SLNB service would be logistical and financial. Prior to the launch of the SLNB program, a proportion of UK surgeons offered axillary sampling (four node sampling) as an alternative to full dissection for patients with early disease. Sampling represented a pragmatic solution to axillary management for the rising numbers of early breast cancers as it offered staging with lower morbidity, comparable early recurrence and survival rates.⁶ With the introduction

of the SLNB procedure, most surgeons performing axillary sampling saw little need to change their practice, whereas surgeons performing axillary clearance were more enthusiastic advocates of the targeted approach to axillary staging.

This survey was initiated with the aim of obtaining a snap shot of the training program and identifying if there are any common barriers that might limit participation and progression in SLNB training.

UK SLNB training

The NEW START program consists of three phases:

(1) *Theory day*: Covers the practical aspects of performing the SLNB procedure, incorporating skills workshops.

This is delivered by 6 regional centres.

(2) *Proctored training*: Supervision of the first 5 SLNB procedures in the participant's own hospital and operating room.

(3) *Validation*: The team performs 25 further cases (total of 30) with prospective centralised data collection.

There are two training routes:

(A) *Model A – for SLNB naïve breast units and surgeons*. A minimum of 30 SLNB cases immediately followed by the units/surgeons standard axillary staging procedure (sampling or clearance): the first 5 cases are supervised by an NEW START accredited trainer in the trainee's own hospital. Out of thirty cases a minimum of 10 must be node positive to allow false negative ascertainment.

(B) *Model B – for SLNB naïve surgeons in breast units where SLNB is the standard of care*. 30 cases are performed under direct supervision of a NEW START accredited trainer who provides written assessment. This model was developed to allow experienced SLNB centres to offer one standard of care during surgeons SLNB training. It represents the more traditional surgical training model but with the addition of built in quality assurance.

Surgeons do not pass or fail the NEW START program. They continue in validation until the set standards are achieved. The validation standards set by the steering committee, based on published data, were:

- Localisation rate 90% (27/30) – data collected for models A and B.
- False negative rate for node positive cases 10% (1/10)- data collected for model A only.

METHODS

A questionnaire was created and received approval from the executive committee of the Association of breast Surgery (ABS) at the British Association of Surgical Oncology (BASO). Electronic and paper copies were sent to the ABS's fully registered members and their responses kept anonymous.

The questionnaire was divided into three sections:

Section 1 - "The Concept" - In this section, surgeons conveyed their preferences for axillary staging clinically node-negative breast cancer patients, and addressed their views on the validity and use of SLNB.

Section 2 - "Training for SLNB" – This section assessed surgeons' progress through the NEW START program, their current training stage, and any problems encountered with the training system.

Section 3 - "SLNB post training" - Concentrated on the various technical aspects of SLNB post training and addressed ongoing audits.

RESULTS

A total of 206 questionnaires were returned, which equates to a total response rate of 52%. The results were blinded from the authors and analysed.

Section 1 – The Concept

The first question addressed surgeons' views on the validity of SLNB. 88% agreed that SLNB is the best surgical option for axillary staging of clinically node negative breast cancer patients. Of the remaining 12%, 3% do not foresee it becoming standard procedure at their centre (table 1). Several surgeons expressed concerns regarding detection of micro-metastatic disease within the SLN and its management, and also variation between surgical approaches leading to the excision of the wrong node; hence false negative SLNB.

The second question explored preferences for the staging of node negative breast cancer patients. A total of 64% of responding surgeons indicated that SLNB is performed as standard practise at their place of work. SLNB is used as a standalone procedure by 23% of surgeons, whilst 41% use it in combination with other treatments, e.g. axillary dissection/sampling. Axillary sampling is performed by 36% of surgeons, axillary radiotherapy performed by 10%, and axillary lymph node dissection performed by 76% (figure 1).

Section 2 – Training for SLNB

A total of 86% of surgeons have completed a NEW START theory day, the majority having done so in 2006. Figure 2 illustrates the year and distribution of centres the surgeons attended. Following the theory day, 29% entered the apprentice model of training (model B). Of the remaining surgeons, 49% have completed the 'in house training' of 5 cases and 41% have completed the validation phase of 30 patients. The remaining 8% of surgeons were either still undergoing in house training, or did not clearly indicate their stage of training. Of the validated surgeons, 96% have achieved the minimum standard, 93% are offering SLNB as a standalone procedure and 48% have applied to the Royal College of Surgeons of England (RCS) to become trainers.

38% of respondents were dissatisfied with the time it took to complete the 'in house' training. Logistical issues were the main reasons cited, for example a lack of on-site nuclear medical facilities and equipment, including gamma detection probes. Difficulties with arranging a regulatory ARSAC licence (Administration of Radioactive Substances Advisory Committee), difficulties within teams and funding issues were other points highlighted by a significant number of respondents (table 2).

Responding surgeons', who were within the validation phase, had performed a median of 12 procedures. Only 13% were satisfied with the time it took to complete this phase. The main reasons for dissatisfaction included the long delay in setting up the program locally, lack of suitable patients, consent issues, and difficulties obtaining equipment (table 2).

The validation phase has been completed by 41% of responding surgeons, with the highest completion rate being in 2007 (35%). Since validation, 17% have performed more than 100 cases, 1% have performed 51-100 and 13% have performed less than 50 SLNB procedures.

Section 3 – SLNB post training

The third section of the questionnaire concentrated on the technical aspects of SLNB following the completion of training. The majority (47%) continue to use dual localisation technique using blue dye and isotope with scintiscan imaging. 39% use isotope and blue dye without imaging, 11% use blue dye alone and 3% use isotope alone (figure 3).

Only 10% offer intra-operative SLN assessment to their patients. Of these, 6% use touch imprint cytology, 3% use frozen sections and 1% use molecular diagnosis with PCR (polymerase chain reaction) technology. The most commonly stated reasons for not performing intra-operative SLNB assessment were logistical constraints (23%), for example lack of an onsite pathologist, a lack of funding and a lack of time. Concerns were also raised about the accuracy of intra-operative diagnosis (table 2). However, several centres reported to be in the process of setting up the necessary infrastructure.

Following completion of the validation phase, surgeons are encouraged by the ABS and NEW START to continue to collect the audit data on their stand alone SLNB procedures. When asked whether they do, 33% of surgeons declined to answer and a further 12% stated that they did not perform ongoing audit. Of the 55% who do continue to collect audit data, 31% included their results in their most recent annual appraisal.

DISCUSSION

In the UK alone, widespread use of SLNB could potentially save over 20,000 women unnecessary axillary dissection and its associated morbidity per year. However by 2003, for a variety of reasons outlined earlier, UK adoption of SLNB was limited to a few specialist centres and training opportunities were restricted.

The NEW START program introduced and set a standard of care in a systematic method. It was unique in the sense that training was validated across a comprehensive national health service, translating specialist standards to every unit in the country, over a relatively short time frame. The NEWSTART progress reports demonstrated excellent early engagement by the surgical community, but progression from theory day training to the validation phase and then to completion was slower than anticipated by the participants.⁷ Anecdotal feedback suggested that despite central government support and communication with individual hospital chief executives, local managerial commitment and lack of resources was an issue even for enthusiastic early adopters.

This survey was conducted 4 years after the introduction of the UK national training program with the aim of assessing how the program was being perceived and adopted, as well as identifying any problems that might hinder uptake and national roll out. It was anonymous and conducted through postal and electronic questionnaires. The 52% response rate was lower than expected, but reflected similar return rates for previous national ABS surveys. It has been noted that those surgeons who have taken part in the NEW START program and are practising SLNB are more likely to have returned the questionnaire.

The data suggests that the majority (97%) of breast surgeons are convinced by the evidence for SLNB, and so most now use SLNB in their practice for staging clinically node negative breast cancer. Other international studies have suggested similar rates of conviction.⁸ The 3% who do not envisage SLNB becoming standard practise are concerned regarding micro-metastatic deposits and how to manage them, and high false negative rates.

There are no clear guidelines in the literature with regards to micro metastatic disease and its management. The indications are that the presence of micro metastases represents an incremental detriment to prognosis with increased risk of non-SLN involvement. There is lack of level 1 evidence concerning its management and current recommendations are that each case requires individual discussion regarding tumour and patient related factors, in the context of the multidisciplinary team.⁹ There is evidence to support that with adequate training, the false negative rate can be kept at approximately 5%, which is no higher than the false negative rate in routine level 1 and 2 axillary lymph node dissection.¹⁰

False negative rates can be influenced by tumour and patient demographics: Increasing body mass index (BMI), tumour location other than the upper outer quadrant and non-visualisation of hot nodes on the pre-

operative lymphoscintiscan all decrease SLNB success. Complete involvement of the SLN with metastatic deposits is another recognised pitfall for false negative SLNB.¹¹

The accuracy of SLNB can be improved using the combined blue dye and isotope technique.¹² This was used by 86% of the respondents, which indicates that the majority of centres followed the recommended guidelines. This is much higher than the NHS breast screening programme (NHSBSP) audit of 2007-08 figures, which report 58% use the combined technique. However, 32% of those audited in the NHSBSP did not indicate the type of SLNB technique used, meaning the figure could be as high as 90%.¹³

Due to lack of on-site nuclear medical facilities several centres could not offer the SLNB imaging in their practice. In a national survey conducted by Quan et al on the national adaptation of SLNB in Canada, lack of access to nuclear medicine facilities and difficulty in obtaining gamma detection probe were similarly amongst the commonest reasons for delay in adaptation of the technique.⁸

According to this survey, 64% of surgeons offer SLNB to their patients. There is clear evidence in literature of the increasing use of this procedure. A survey in 2001/02 demonstrated only 17% of surgeons used SLNB routinely in the UK, in combination with other procedures.¹⁴ A 2006 study showed 52% of surgeons used the technique, suggesting a 12% increase in the use of SLNB over two years, which demonstrates the impact of the NEWSTART national training program. These figures also correlate with international figures, for example a Canadian study on the uptake of SLNB suggested a rate of use of 62% in Canada.^{8, 15}

Intra-operative diagnosis (IOD) of the SLN is currently only performed by a small number of respondents (10%), despite increasing evidence suggesting its efficacy.¹⁶ This probably reflects the lack of UK experience in SLNB as intra-operative assessment represents a natural progression in the maturation of SLN biopsy world-wide. IOD requires considerable pathological expertise and time - for centres struggling to introduce basic SLNB, this may be one step too far. Reasons described by respondents for not performing IOD included an absence of onsite pathologists and lack of evidence in its cost effectiveness.

Those who have completed the in house proctoring phase are generally satisfied with the time it takes to complete the phase; however the majority of validated surgeons are dissatisfied with the time it takes to become fully validated. The reported delay in completion of the program is mainly due to logistical issues, with problems such as lack of facilities, equipment and funding being encountered. Lack of on-site nuclear medical facilities and equipment, including gamma detection probes were amongst common reasons expressed by the respondents.

These issues cannot be resolved or altered by NEW START. Instead, the Department of Health and the National Health Service (NHS) Trusts need to look closely at the logistics and funding of breast units to enable surgeons to train and carry out the SLNB procedure as recommended. This will ensure that this powerful technique is

universally available to all breast cancer patients. Furthermore, the expansion and implementation of the NEW START program may help guide future postgraduate surgical education programs.

CONCLUSION

The NEW START program introduced and set a standard of care in a systematic method. It was unique in the sense that training was validated across a comprehensive national health service, translating specialist standards to every unit in the country, over a relatively short time frame. The majority of breast surgeons in the UK are convinced by the evidence for SLNB, and so most now use SLNB in their practice for staging clinically node negative breast cancer. Reasons for not conducting SLNB or IOD are logistical rather than lack of belief in the procedure. Barriers to uptake and progress were as expected - logistical and financial rather than attitudinal. The majority of respondents who completed their training did so within the anticipated time line. The majority of centres do not perform intra-operative assessment of the SLN due to lack of resources which means node positive patients have to undergo a second operation.

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Figures and Tables

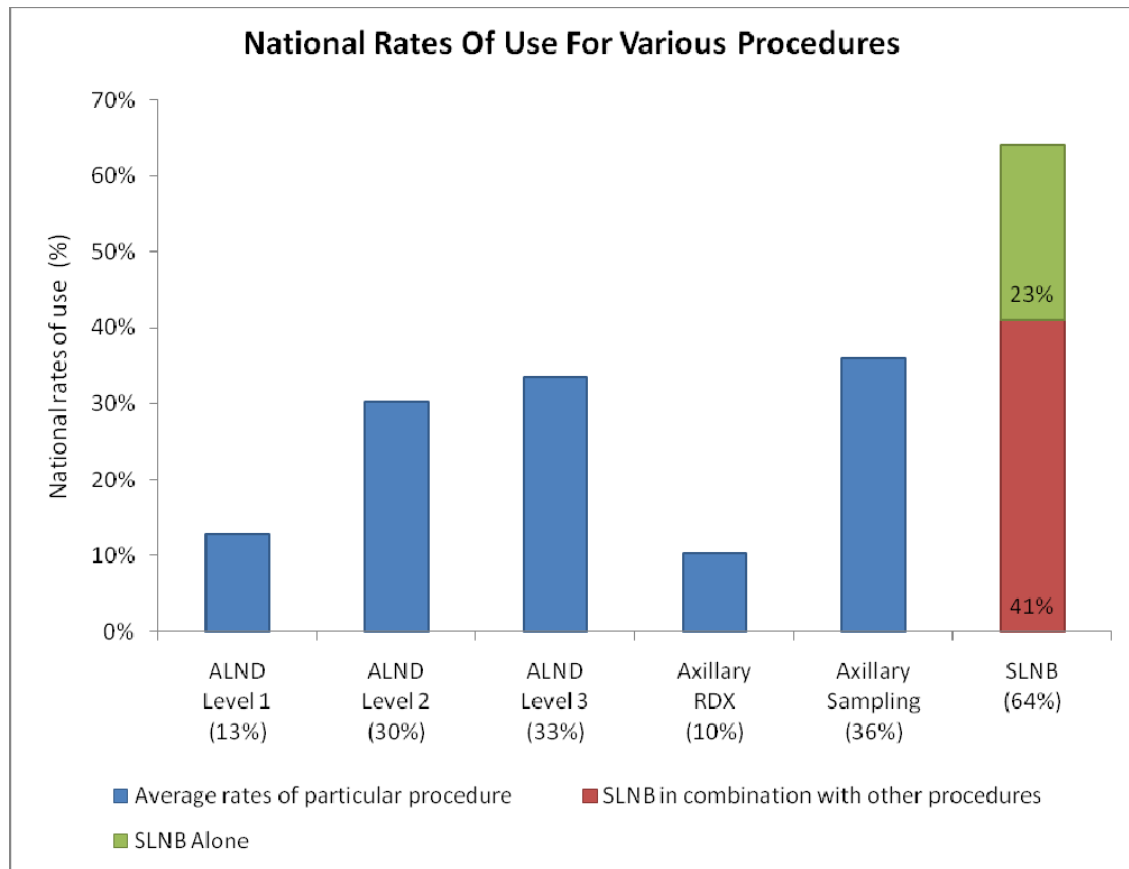


Figure 1: National usage rates of various surgical methods

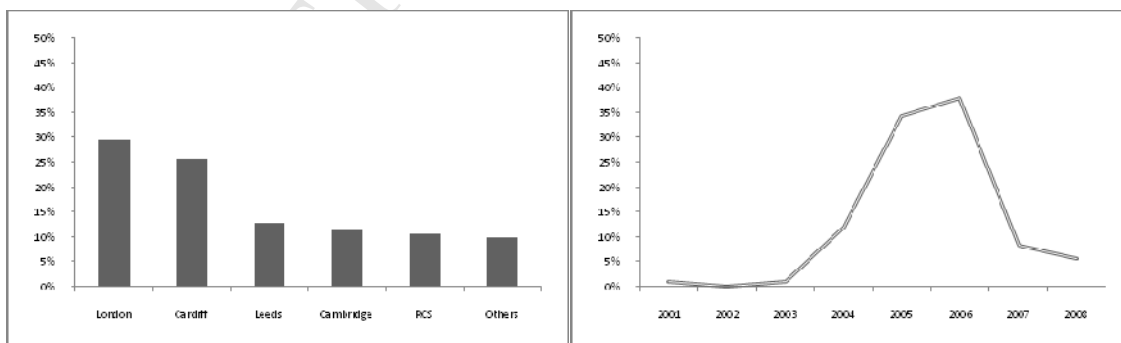


Figure 2: Distribution of centres and dates where theory day was completed

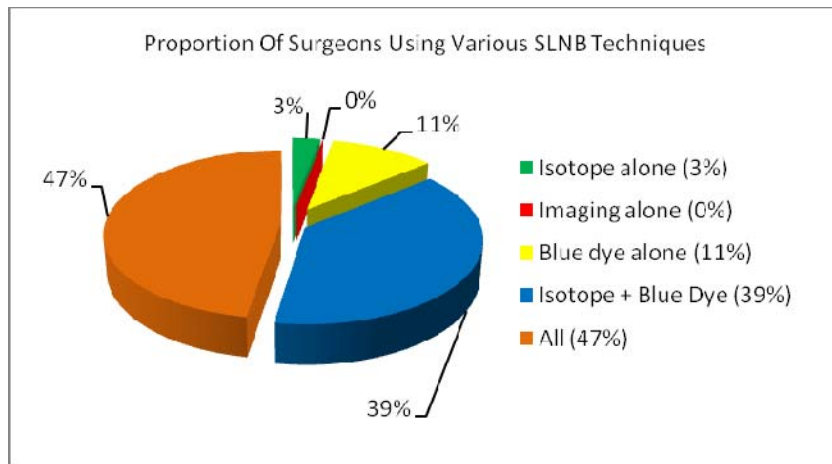


Figure3: *Proportion Of Surgeons Using Various SLNB Methods*

In house training	Lack of nuclear medical facilities	34%
	Lack of equipment	31%
	Difficulties with ARSAC licence	19%
	Difficulties within team	17%
	Funding issues	15%
Validation phase	Time to set up program	40%
	Lack of suitable patients	38%
	Difficulties obtaining equipment	30%
	Not able to achieve minimum standard	10%
	Funding	5%

TnQTable1Table 1: *Problems with the in house training and validation phases*

Proportion of surgeons using intra operative diagnosis	Yes 10%	Touch imprint cytology	6%
		Frozen section	3%
		Molecular diagnosis	1
	No 90%	Logistical issues	23%
		Funding	19%
		Too much time	18%
		Lack of accuracy	15%

TnQTable2Table 2: *Proportion of surgeons using intra-operative diagnosis*