LETTERS

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SENTINEL NODE BIOPSY FOR MELANOMA

Call for a balanced view on SNB

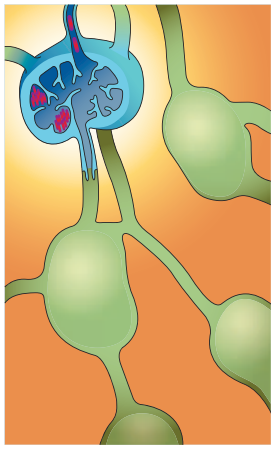
The title of Torjesen's article could be misleading.[1] Sentinel node biopsy (SNB) is a staging tool used to provide patients with the best available information,[2] and is a well established prognostic test.

Our research shows that patients want information on prognosis.[3] Lymph node status is the most meaningful prognostic indicator and SNB the most sensitive test. Perhaps the addition of the word "test" would be helpful. Early identification and removal of affected lymph node basins can provide local disease control and psychological benefit for patients. The first Multicenter Selective Lymphadenectomy Trial found some benefit in terms of disease-free survival, which should not be ignored.

Arguments for and against the use of SNB have been carefully considered by numerous groups around the world. The usefulness, accuracy, and low risk of harm are well established. Early clearance of microscopically affected, but non-palpable, lymph node basins with lower tumour load has reduced the morbidity of block dissection surgery.[4]

Breast cancer is a different disease and the technique itself is different from melanoma SNB. This can lead to confusion for those reviewing the publications on SNB.

SNB for melanoma is offered to eligible patients at Guy's and St Thomas' melanoma clinic. The reasons, risks, benefits, and information on appropriate clinical trials are given, as recommended by the recent best practice pathway.[5]



CLAUDIA BENTLEY

Finally, and crucially, we perform SNB to enable accurate staging and enrolment of patients to adjuvant drug trials and other research trials with the aim of improving overall treatment. We urge readers to take a more balanced view than that presented by Torjesen.

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Competing interests: We offer sentinel node biopsy and enrol patients to MSLT 2.

The full response is at www.bmj.com/content/346/bmj.e8645/rr/625240.

1 Torjesen I. Sentinel node biopsy for melanoma: unnecessary treatment? *BMJ* 2013;346:e8645. (8 January.)
2 Balch CM, Gershenwald JE, Soong S-J, Thompson JF, Atkins MB, Byrd DR, et al. Final Version of 2009 AJCC Melanoma Staging and Classification. *J Clin Oncol* 2009;27:6199-205.
3 Constantinidou A, Afuwape SA, Linsell L, Hung T, Acland K, Healy C, et al. Informational needs of patients with melanoma and their views on the utility of investigative tests. *Int J Clin Pract* 2009;63:1595-600.
4 Faries MB, Thompson JF, Cochran A, Elashoff R, Glass EC, Mozzillo N, et al; MSLT Cooperative Group. The impact on morbidity and length of stay of early versus delayed complete lymphadenectomy in melanoma: results of the Multicenter Selective Lymphadenectomy Trial (I). *Ann Surg Oncol* 2010;17:3324-9.
5 Melanoma Taskforce (chaired by James S). Quality in melanoma care: a best practice pathway. 2012. www.bapras.org.uk/downloaddoc.asp?id=856.

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Where is the evidence base?

Sentinel node biopsy (SNB) has been promoted by claims of a survival advantage after early lymphadenectomy in patients with a positive result. The pivotal paper states that SNB "identifies patients with nodal metastases whose survival can be prolonged by immediate lymphadenectomy."[1] An earlier paper by Morton and colleagues states, "Our data suggest a significant therapeutic benefit for immediate dissection based on identification of tumour-involved sentinel node."[2] Accurate statistical analysis[3] does not support those statements, and the claim that SNB offers a disease-free survival advantage.[1] An appeal on this matter to the National Institutes of Health in 2007 was upheld. Morton was asked to include distant disease-free survival as an endpoint in the next update of the trial.[3] The final results of the first Multicenter Selective Lymphadenectomy Trial (MSLT-1) could have been published in May 2010. Why has this not happened?

Other central claims, such as sentinel node status being essential for accurate staging and early lymphadenectomy facilitating regional disease control,[4] are equally inaccurate.

This pretence is sustained by vested interest and citation distortion. None of the main protagonists of SNB, who hold powerful positions in academia, learned societies, and journals, especially in the US, have ever cited the main publication challenging the statistical accuracy of MSLT-1.[3] This has allowed presentation and publication selection, resulting in a biased message. Many protagonists have put all their clinical and research eggs in the SNB basket, and discrediting the subject would be highly inconvenient. To quote Upton Sinclair, "It's difficult for a man to understand something if his salary depends on him not understanding it." Torjesen is correct.[5] Publish the final results of MSLT-1.

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Competing interests: None declared.

The full response is at www.bmj.com/content/346/bmj.e8645/rr/625654.

1 Morton DL Thompson JF, Cochran AJ, Mozzillo N, Elashoff R, Essner R, et al; MSLT Group. Sentinel node biopsy or observation in melanoma. *N Engl J Med* 2006;355:1307-17.
2 Morton DL, Hoon DS, Cochran AJ, Turner RR, Essner R, Takeuchi H, et al. Lymphatic mapping and sentinel lymphadenectomy for early-stage melanoma. *Ann Surg* 2003;238:538-49.
3 Thomas JM. Concerns relating to the conduct and statistical analysis of MSLT-1. *J Plast Reconstr Aesthet Surg* 2009;62:442-6
4 Wong SL. Sentinel lymph node biopsy for melanoma: ASCO and SSO joint clinical practice guidelines. *Ann Surg Oncol* 2012;19:3313-24.
5 Torjesen I. Sentinel node biopsy for melanoma: unnecessary treatment? *BMJ* 2013;346:e8645. (8 January.)

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TRIAL REGISTRATION AND PUBLICATION

Encouraging steps in the UK

An impressive 98% of studies funded by the National Institute for Health Research Health Technology Assessment (HTA) Programme are published.[1] To put this into context, I contacted the Medical Research Council (MRC) and the three largest medical charities that support research—the Wellcome Trust, Cancer Research UK, and the British Heart Foundation.

They all responded and acknowledged that future publication was not a mandatory requirement for funding. One major difficulty was tracking publications long after a trial had finished, but this is now being tackled with the use of online registers.

The British Heart Foundation requires all trials to register with the UK Clinical Research Network (UKCRN) and produce annual reports. It is also considering a formal mechanism to incentivise publication, such as withholding payment.

Cancer Research UK requires clinical trials to be registered on ISRCTN (International Standard Randomised Controlled Trial Number) or ClinicalTrials.gov and also tries to provide a lay summary of results from all trials on its website.

The MRC states that the findings of MRC funded research must be made available to the research community and the public.[2] It also helped to set up ResearchFish with other funders to collect information on the outcomes of research.

Finally, the Wellcome Trust requests that all randomised controlled trials be registered. It also retains 10% of grant funding until an end of grant report is submitted. Publication is encouraged but not necessary.

Research funders have taken encouraging steps in recent years, and it is hoped that the HTA's example will inspire further progress.

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1 Chalmers I, Glasziou P, Godlee F. All trials must be registered and the results published. *BMJ* 2013;346:f105. (9 January.)
2 Medical Research Council. Good research practice: principles and guidelines. 2012. www.mrc.ac.uk/consumption/groups/public/documents/content/mrc002415.pdf.

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Under-reporting is a big issue

Chalmers and colleagues state that under-reporting of research "leads to overestimates of the benefits of treatments and underestimates of their harmful effects."[1]

The extent of the problem should not be underestimated. A 2010 study of 546 drug trials, conducted between 2000 and 2006, reported that only 66% had published their results. Rates of trial publication within 24 months of study completion ranged from 32% in industry funded trials to 56% in those funded by non-profit or non-federal organisations.[2]

The situation does not seem to have improved much since then. Analysis of trials listed on ClinicalTrials.gov found that only 46% of 677 trials completed by 2007 were published in a peer reviewed Medline listed biomedical journal within 30 months of trial completion.[3] Mandatory reporting of trials seems to have made little difference. The overall rate of compliance with the mandatory reporting rate for 2009 trials listed on ClinicalTrials.gov within one year of completion is only 22%.[4] A further study of ClinicalTrials.gov data from 2009 to 2010 reported that only 52% of 152 trials had associated publications within two years of posting.[5]

The size and problems associated with under-reporting of trials are substantial and continuing. Mandatory reporting has failed to resolve the matter, and finding a solution should be a priority for healthcare.

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Competing interests: None declared.

1 Chalmers I, Glasziou P, Godlee F. All trials must be registered and the results published. *BMJ* 2013;346:f105. (9 January.)
2 Bourgeois FT, Murthy S, Mandl KD. Outcome reporting among drug trials registered in ClinicalTrials.gov. *Ann Intern Med* 2010;153:158-66.
3 Ross JS, Tse T, Zarin DA, Xu H, Zhou L, Krumholz HM. Publication of NIH funded trials registered in ClinicalTrials.gov: cross sectional analysis. *BMJ* 2012;344:d7292.
4 Prayle A, Hurley M, Smyth AR. Compliance with mandatory reporting of clinical trials results on ClinicalTrials.gov: cross sectional analysis. *BMJ* 2012;344:d7373.
5 Zarin DA, Tse T, Williams RJ, Califf RM, Ide NC. The ClinicalTrials.gov results database—update and key issues. *N Engl J Med* 2011;364:852-60.

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HOW TO ACT WHEN YOU SHOULD

Principles for surgical wards

Hopkins's experience is in no way unusual.[1] In many units there is no scheduled visiting by junior staff and the "business" ward round by consultant or registrar does not happen.

I suggest that the following principles are applied in all surgical wards:

- All patients should expect a visit from their surgeon on the day after surgery. If this is not possible the surgeon must ensure that a nominated doctor will visit instead
- All patients must be seen at least once by a doctor every day that they remain in hospital.

These were the normal working practices when I qualified in 1969 and were the principles that I followed until I retired. This is also the standard expected in the private sector.

I was also fortunate to work with anaesthetists who made a point of visiting patients after surgery. I understand that this may not now be the norm.

If there is a complication after surgery, the consultant surgeon or anaesthetist is responsible. All surgeons realise this and, in my view, they are responsible for making sure that their patients are seen by themselves, their colleagues, or the appropriate junior staff.

If these simple standards cannot be met then surgery should be deferred until the infrastructure is in place.

The multidisciplinary team is essential for modern surgery, but the operating surgeon is the leader and the person who, with his anaesthetic colleagues, must carry the can. Hopkins's article describes the "system" failing. Such failures can be avoided by following the two principles above.

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Competing interests: None declared.

1 Hopkins R, Werrett G. How no one acted when they should have. *BMJ* 2012;345:e5366. (16 August.)

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SLEDGING INJURIES

Sledges are snow joke

The recent snow fall seriously affected the running of our general hospital service. Difficulties of staff, patients, and provisions getting to the hospital led to cancelled operations, high clinic non-attendance rates, and problems with staffing in the clinical and support settings. The icy weather also brought the expected increased number of falls causing fractures, bruises, and strains.

We also saw an increase in sledging injuries and an increased workload associated with this "gentle" recreational sport.[1] The impact was felt especially in the emergency, orthopaedics, and general surgery departments. Interestingly, a large number of injuries were associated with sledging at night or after the consumption of alcohol.

Within three days we saw 20 orthopaedic injuries caused by sledging, which occurred in all age groups and varied in severity from minor fractures to serious injuries.

In general surgery, one patient had a ruptured spleen and needed a splenectomy, and another had a de-gloving injury of the scrotum and buttocks. In a previous cold spell, a patient died after hitting a tree at speed.

We therefore emphasise the dangers of sledging and recommend that it is avoided in poor light and after drinking alcohol.

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Patient consent obtained.

1 Cohen B, Shewring D, Chapman P. Sledging injuries. *BMJ* 1991;302:596.1.

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