The thought-provoking article ‘Margins for error’ by Dr P. J. Heenan proposes that surgeons abandon the results of prospective clinical trials and, instead, adopt a 1-cm surgical margin for excising all melanomas, regardless of their thickness or other prognostic features.1 I could not agree with this recommendation, based upon current scientific evidence from surgical trials. On the other hand, it is a reasonable hypothesis to test in a prospective clinical trial. Ultimately, Dr Heenan might be correct, but there is no evidence to support his recommendation at present.

Are we over-treating our melanoma patients with a 2-cm margin instead of a 1-cm margin of excision?2 If, in fact, surgeons are over-treating melanomas by excising them with an extra 1 cm or so of skin, the consequences are minimal, because in almost all circumstances, the surgical defect can be closed primarily (i.e. without a skin graft). On the other hand, a local recurrence from melanoma is often the harbinger of a fatal metastases, so if we under-treat melanomas with narrow surgical margins, the patient might lose their life! There are three decades of prospective surgical trials that provide evidence-based guidelines that shape the standards of care regarding surgical margins for melanoma.2–7 More conservative surgical margins than those in place today should only be performed if subsequent surgical trials demonstrate that it is safe to do so.

Here is what we do know about surgical margins for melanoma: (i) a local recurrence is associated with a high mortality rate (estimated at 80–90%); (ii) local recurrence rates for melanomas correlate significantly to four features of the primary melanoma – thickness, presence or absence of ulceration, anatomical site, and growth pattern; (iii) prospective randomized surgical trials have clearly demonstrated safety with regard to a 1-cm margin for melanomas of 1 mm or less in thickness, while a 2-cm surgical margin is safe for intermediate-thickness melanomas (i.e. 1–4 mm thickness); (iv) there is still some debate about whether a 1-cm margin is relatively safer than a 2-cm margin for melanomas of 1–2 mm thickness; (v) a non-randomized trial is demonstrated safety for a 2-cm surgical margin for melanomas exceeding 2 mm in thickness and; (vi) almost all surgical incisions in melanomas with a 1–2 cm radial margin of skin, can be performed as outpatient surgery without a disfiguring skin graft.3,5,7,8

Here is what we don’t know about surgical margins for melanoma: (i) whether a local recurrence (LR) is caused by retained primary melanoma cells that metastasized before clinical detection, or whether they are the first manifestation of circulating distant skin metastases that fortuitously arise in or around the surgical scar; (ii) whether local recurrence rates actually do correlate to the extent of surgical margins; (iv) whether a 1-cm surgical margin is safe for melanomas exceeding 1–2 mm in thickness, especially those that are ulcerated; and (iv) whether particular growth patterns, especially acral lentiginous melanoma (ALM), lentigo maligna melanoma (LMM) or desmoplastic melanomas (DM) are safe to excise with reduced surgical margins as no clinical trial has specifically addressed these patients groups.9,3

It seems appropriate to use local recurrence rates as one benchmark for evaluating the results of clinical trials involving surgical margins for melanoma, as we cannot distinguish between local recurrences that arise from retained primary melanoma cells and those that arise from circulating distant metastases. This is especially true for thicker and ulcerated melanomas where the local recurrence rates were 10–15% or more in the Intergroup Melanoma Surgical Trial.2,3,4 Thus, the influence of ulceration on local recurrence rates was striking: the incidence of LR increased six-fold compared to non-ulcerated melanomas of intermediate thickness; it increased four-fold as the melanoma thickness increased from 1 to 4 mm; and it was higher again for melanomas arising on the head and neck area compared to other anatomical sites. Overall, the incidence of LR in the Intergroup Melanoma Trial was lower than that of the World Health Organization (WHO) Melanoma Trial for the overlapping 1- to 2-mm thickness patients (4.5% LR for the WHO Trial 10 vs 0.6% for the Intergroup Trial). Therefore, I would recommend a 2-cm surgical margin for these melanomas (i.e. 1–2 mm in thickness) whenever it is anatomically feasible and where the surgical defect can be closed primarily without a skin graft. For all melanomas > 2 mm in thickness, the data from prospective clinical trials convincingly demonstrate that this is a safe and appropriate radial surgical margin to use.3,7 Finally, surgical trials have confined their patient eligibility to patients with superficial spreading and nodular growth patterns, so we have little data about the influence of surgical margins on other growth patterns, including ALM, LMM and DM. The surgical excision of ALM is particularly difficult when they arise from the soles and palms, since it is difficult to discern the exact lateral margin of the melanoma that is covered by a thickened epidermis.10,11 A desmoplastic melanoma has a particularly high rate of local recurrences, and it seems prudent to excise these melanomas with both wide and deep margins, along with consideration of local adjuvant radiation.12

In summary, 30 years of prospective surgical trials have allowed us to safely reduce surgical margins without causing harm to our patients. Can we be even more conservative in our surgical margins? In my opinion, we should not establish guidelines for reduced margins arbitrarily based upon an unproven hypothesis. However, it would be appropriate to test such a hypothesis to reduce surgical margins based upon a prospective randomized surgical trial. Arguing that melanoma margins should be more conservative today, makes no more sense than the statements of our predecessors who argued that surgical treatment of melanoma should be more radical; neither is based upon an adequate level of scientific evidence. To adopt treatment guidelines without evidence might cause potential harm to our patients. Adopting 1-cm surgical margins as ‘standards of care’, should be reserved for a future time if, in fact, results from subsequent prospective surgical trials demonstrate that it safe and efficacious.

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EDITORIAL

EXPLORATION OF THE COMMON BILE DUCT IN THE ERA OF LAPAROSCOPIC CHOLECYSTECTOMY

A decade ago, the operative practice of general surgery was revolutionized by the development of laparoscopic cholecystectomy. This procedure has now largely replaced the traditional open surgical approach for the management of gallstone disease, and its success has encouraged the further development and dissemination of laparoscopic approaches for the management of other intra-abdominal disease processes. Paradoxically, however, the wide uptake of laparoscopic cholecystectomy has been accompanied by controversy about how to best manage the associated problem of common bile duct calculi. In part, this is because laparoscopic cholecystectomy is within the skill range of most practising general surgeons, whereas laparoscopic approaches to common bile duct exploration are more difficult, have been less widely disseminated, and a standard approach to the problem of common bile duct calculi has not yet emerged.

In the previous era of open surgery there was little, if any, controversy about the management of common bile duct calculi. If calculi were identified by operative cholangiography at the time of open cholecystectomy, then a choledochotomy was usually fashioned, and the calculi were removed directly from the common bile duct. A T-tube was then placed into the common bile duct, and the choledochotomy was closed around it. While there were some variations to this approach (including primary closure of the common bile duct without T-tube drainage, and transduodenal sphincteroplasty with extraction of calculi via the duodenum), the overall concept of dealing with calculi at the same time as cholecystectomy (i.e. a single procedure) was considered to be appropriate and safe. Endoscopic retrograde cholangiopancreatography (ERCP) had a role in achieving duct clearance when this strategy failed.

If laparoscopic approaches to the management of common bile duct calculi were simple, then a similar treatment algorithm would almost certainly still be followed now. However, this is not the current situation in Australia and New Zealand, and general surgeons are now faced with a plethora of choices and a lack of agreement about how to best manage common duct calculi. Current options include ERCP (either before, during or after surgery), conversion to open surgery for duct exploration, laparoscopic common bile duct exploration via the cystic duct, or exploration via a laparoscopic choledochotomy. Which approach is applied perhaps better reflects the operating surgeon’s technical skills rather than a carefully considered evidence-based approach applied to the clinical situation. Evidence from two randomized trials1,2 which enrolled 80 and 300 patients respectively and compared an ERCP-based management approach with laparoscopic duct exploration using a mixture of transcystic and choledochotomy approaches, demonstrated similar duct clearance rates and morbidity for the management strategies evaluated, but a shorter overall length of hospital stay, fewer overall procedures, and a trend towards less overall procedure time with laparoscopic common bile duct exploration. Both trials confirm that we should not be in a rush to abandon the time-proven algorithm of common bile duct exploration when common bile duct calculi are encountered at the time of cholecystectomy, although whether the outcomes from the trials can be realistically extrapolated to the practice of the average general surgeon might be questioned.

Most general surgeons, however, do not regularly apply laparoscopic suturing techniques, and for this reason the use of a laparoscopic choledochotomy has been restricted. Transcystic
exploration was advocated as a way of simplifying duct exploration, and this technique can result in duct clearance rates of more than 50% without resorting to choledochotomy. Nevertheless, even this approach can be challenging for surgeons who only manage common bile duct stones occasionally. For these reasons, the contribution of Martin et al.\textsuperscript{3} is welcome. Placement of a stent via the cystic duct as described in their paper is unlikely to require technical expertise beyond that which most general surgeons performing laparoscopic cholecystectomy already possess, and it is likely that any subsequent ERCP with endoscopic sphincterotomy will be performed more reliably by cutting directly onto the surgically placed stent, thereby facilitating a higher success rate for postoperative ERCP. The use of this approach perhaps better reflects the current realities of Australasian surgery: most surgeons performing laparoscopic cholecystectomy are not exploring the common bile duct laparoscopically. However, whether such an approach is cost-effective is open to debate and the need for two or more interventional procedures may be a significant disadvantage when compared to laparoscopic common bile duct exploration. Hopefully with time, advanced laparoscopic surgery techniques will be better incorporated into our surgical training programmes, and a higher level of advanced laparoscopic expertise will develop. If this happens, then laparoscopic common bile duct exploration could become the preferred management strategy for common bile duct calculi, and the approach of Martin et al.\textsuperscript{3} might then be best reserved for patients for whom duct exploration has either failed, or is inappropriate.

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REFERENCES