

## Short Communication

### Ambulatory Narrow Excision for Thin Melanoma ( $\leq 2$ mm): Results of a Prospective Study

A. Bono,<sup>1</sup> C. Bartoli,<sup>1</sup> C. Clemente,<sup>2</sup> I. Del Prato,<sup>1</sup> P. Boracchi,<sup>3</sup> N. Rossi<sup>4</sup> and N. Cascinelli<sup>5</sup>

<sup>1</sup>Division of Surgical Semiotics and Ambulatory Surgery; <sup>2</sup>Division of Anatomic Pathology and Cytopathology, Istituto Nazionale Tumori, Via Venezian 1, 20133, Milan; <sup>3</sup>Institute of Medical Statistics and Biometrics, University of Milan; <sup>4</sup>Division of Medical Statistics and Biometrics; and <sup>5</sup>Division of Surgical Oncology B, Istituto Nazionale Tumori, Milan, Italy

Although narrow surgical excision may be sufficient for thin melanoma, questions remain concerning how narrow the excision should be and how it should be related to tumour thickness. To address these issues, a group of 168 consecutive patients with primary invasive melanoma up to 2 mm thick underwent ambulatory surgery with excision margins of 1 cm. 40 (24%) of these patients had lesions thicker than 1 mm. In a median follow-up of 5 years, 11 patients relapsed and 3 developed second malignancies. The crude cumulative incidence of regional and distant metastases were, respectively, 5.6% and 1.5%. No local isolated recurrence was observed, indicating that ambulatory narrow excision is justified for melanoma up to 2 mm thick. © 1997 Published by Elsevier Science Ltd.

**Key words:** cutaneous melanoma, thin melanoma, treatment

*Eur J Cancer*, Vol. 33, No. 8, pp. 1330–1332, 1997

#### INTRODUCTION

THE SURGICAL treatment of cutaneous melanoma is currently based on a good understanding of the biology of the disease along with observations of its clinical course. The approach has become increasingly conservative by the fact that clinical data have confirmed a strict relationship between stage and outcome, so that early melanoma is highly curable [1].

Since May 1987, at the Division of Diagnostic Oncology and Outpatient Clinic of the Istituto Nazionale Tumori of Milan, patients with clinically stage I thin cutaneous melanoma have been treated by outpatient surgery. This treatment policy was undertaken after the safety of a conservative excision of 'thin' melanomas was suggested by Veronesi and associates in a prospective randomised study conducted under the auspices of the World Health Organization [2, 3].

In our study, performed in a routine setting, we included patients with primary invasive melanoma not thicker than 2 mm. These patients were judged to be proper candidates

for curative narrow excision (1 cm margin). The results of our experience are herein presented.

#### PATIENTS AND METHODS

Between May 1987 and December 1991, 190 consecutive patients with clinical stage I invasive melanoma 2 mm thick or less, all diagnosed and operated on at the outpatient department of our Institution, were considered for participation in the study. Criteria of exclusion were: inadequate surgical excision of the primary (5 cases); lack of postoperative follow-up (2 cases); multiple primary invasive melanomas (15 cases). The study sample was therefore 168 cases.

These patients were ambulatory treated, under local anaesthesia, with excision margins of 1 cm, and the subcutaneous fat was cleared to the deep fascia, which was generally conserved. Loss was made good by direct tissue closure, except 3 cases which required reparative plastic surgery. 85 patients had an excision biopsy before definitive surgery and 83 had only definitive excision.

All patients were followed prospectively. A full physical examination was always performed and patients also underwent thoracic X-ray and liver ultrasound examination once a year. Patients with lesions not thicker than 1 mm were seen at 6-monthly intervals; the others were seen at 4-monthly intervals for the first 3 years and 6-monthly inter-

Correspondence to A. Bono.

Received 27 Aug. 1996; revised 9 Dec. 1996; accepted 17 Jan. 1997.

vals thereafter. The median follow-up was 62 months (range 18–106 months).

The pattern of relapse-free survival (RFS) was estimated by means of the product limit method (Kaplan and Meier) on the basis of a 5-year follow-up period. The RFS was defined as the period from surgery until the date of the first neoplastic event (local relapse, regional metastases, metastases in transit, distant metastases and other neoplasia) or the date of last clinical examination. Since these neoplastic events were not independent for each event, the crude cumulative incidence, and its 95% confidence interval at 5 years, was obtained following a competitive risk approach [4]. When no specific neoplastic events occurred, the confidence interval for the annual rate of 0% was obtained by the exact procedure (data from the Documenta Geigy-Tables Scientifiques).

## RESULTS

Of the 168 patients, 63 (37.5%) were men and 105 (62.5%) were women, with the median age at initial presentation of 50 years. The site of the lesions was head and neck in 11 cases, trunk in 78, lower limb in 58 and upper limb in 21.

Of the 168 melanomas, 128 (76%) were no thicker than 1 mm and 40 (24%) had a thickness of between 1 and 2 mm.

On the basis of 5 years' follow-up, the RFS curve of 168 patients is shown in Figure 1. The 5-year probability of remaining free of recurrence was 91% (88.2–100%). Figure 2 shows the RFS curve according to the thickness of the tumours.

11 patients had a relapse of their melanoma and 3 patients developed other neoplasms. The most frequent first negative event was regional lymph node metastases, which were observed in 9 patients, 4 of whom had had melanoma no thicker than 1 mm. (These were the only relapses of the 128 with melanoma  $\leq 1$  mm thick.) 2 patients had distant metastases as sites of first relapse. Of these 11 relapsed patients, 1 with lymph node and 1 with distant metastases (both affected by a primary lesion thicker than 1 mm) had a

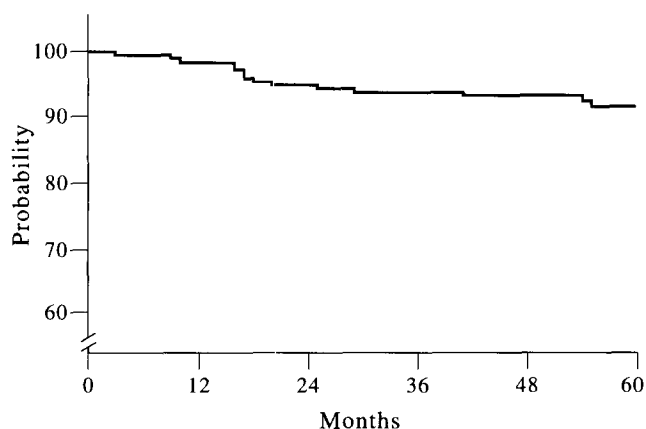


Figure 1. Relapse-free survival of 168 patients with melanoma  $\leq 2$  mm thick.

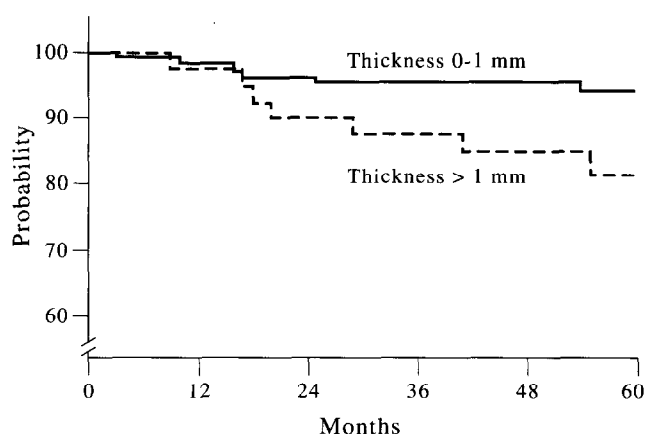


Figure 2. Relapse-free survival according to tumour thickness of 168 patients with melanoma  $\leq 2$  mm thick.

concomitant local recurrence. The latter case also had regional nodal metastases.

The crude cumulative incidence of regional metastases was 5.6% (2.0–9.2%) and the crude cumulative incidence of distant metastases was 1.5% (0–3.7%). The annual rate of local recurrence was 0% (0–3.69%).

## DISCUSSION

During the past decade, the proper width of resection margins from primary melanoma have been widely debated. Historically a radical excision with 3–5 cm margins of normal skin from the borders of the tumour was considered the optimal excision for all cutaneous melanomas. This statement was based on the belief that the therapeutic results would be improved by excising local lymphatic spread along with the tumour. The ablation of the deep fascia would ensure removal of the soft tissue lymphatics. Subsequent study showed that excision of the deep fascia does not alter the clinical course of the disease [5]. By introducing micro-staging [6] and the appreciation that prognosis is related to tumour thickness, wide margins of excision are no longer a dogma [7–9]. Local recurrences after treatment are very low for lesions less than 1 mm thick [10]. Moreover, the presence of microsatellitosis are rare for lesions no thicker than 2 mm [11]. These observations tend to suggest the curability by limited surgery of melanomas less than 2 mm thick.

On clinical grounds, these observations are in agreement with the results of Veronesi and associates [2, 3]. The authors compared the results of narrow excision (1 cm margin) performed in 305 patients with those of wide excision (3 cm margins) performed in 307 patients, all with melanoma up to 2 mm thick. After a mean follow-up of 55 months, disease-free, overall survival and local recurrence rate were not significantly different. Local recurrence developed in 6 patients, with only site of relapse in 3, all lesions thicker than 1 mm, treated by conservative surgery [2]. At a mean follow-up of 90 months [3], again there were no significant differences in either disease-free and overall survival among the two groups. Isolated local recurrences were reported in 4 patients, all with melanomas thicker than 1 mm included in the narrow-excision group. A recent update [12] reports a single isolated local recurrence in the

wide-margin group and 5 local recurrences in the narrow-margin group, all of them after excision of tumours thicker than 1 mm. The long-term results of the trial showed that it is safe to excise melanomas <1 mm thick with a 1 cm margin, but could not reach definitive conclusions about the surgical margins for melanomas thicker than 1 mm. Better results about local control of the disease were obtained by Balch and associates [13] with a prospective randomised trial to compare 2 and 4 cm margins for melanomas 1–4 mm thick. The median follow-up time for this study was 72 months, but the shortest length was not recorded. One isolated local recurrence was reported among the 58 patients with melanomas 1–1.99 mm thick treated by 2 cm margin. These results compare with those of a retrospective study of 5 cm excision margins, which included 147 patients with 1–1.9 mm thick melanomas who had 2% local recurrence after a minimum 5 years' follow-up [14]. Therefore, an excision with wide margins would not prevent a local recurrence in a proportion, albeit small, of cases.

Our results, particularly because they are from a series of patients from one centre, encourage a conservative surgical approach for all melanomas up to 2 mm thick.

The relapse-free survival compares favourably with that reported in the WHO study at the same period of follow-up. We had no isolated local recurrences. This prompts us to maintain that an excision margin of 1 cm is justified for melanoma up to 2 mm thick. However, we accept that results from a longer follow-up period are necessary to confirm this policy.

Our data emphasise once more the concept that distant disease is not linked to the width of excision when reasonable margins are used, but to other factors such as thickness of the tumour. In fact, as expected, patients with primary melanomas no thicker than 1 mm had a better prognosis than those with thicker tumours (Figure 2).

The results of other authors support the efficacy of narrow excision. O'Rourke and Altmann [15], through a retrospective analysis of 187 patients with thin, intermediate and thick melanoma, report no significant difference in recurrence rate associated with excision margins of 15 mm or less compared with wider margins. Moreover, in another study, O'Rourke and Bourke [16] advocate a 1 cm excision margin irrespective of tumour thickness. These authors prefer general anaesthesia when performing the operation, with a 4-h admission to a day-surgery centre.

Our results emphasise the benefits of the adopted surgical procedure. It can be performed in an outpatient setting using local anaesthesia, allowing for a primary wound closure, with good cosmetic results. Outpatient surgery is appreciated by the patients, it reduces the psychological stress

associated with admission, keeping costs and resource allocation to a minimum.

1. Rigel DS, Rogers GS, Friedman RJ. Prognosis of malignant melanoma. *Dermatol Clin* 1985, **3**, 309–314.
2. Veronesi U, Cascinelli N, Adamus J, *et al.* Thin stage I primary cutaneous malignant melanoma; comparison of excision with margins of 1 or 3 cm. *N Engl J Med* 1988, **318**, 1159–1162.
3. Veronesi U, Cascinelli N. Narrow excision (1-cm margin). A safe procedure for thin cutaneous melanoma: effect on recurrence and survival rates. *Arch Surg* 1991, **126**, 438–441.
4. Marubini E, Valsecchi MG. *Analysing Survival Data from Clinical Trials and Observational Studies*. Chichester, John Wiley, 1995.
5. Kenady DE, Brown BW, McBride CM. Excision of underlying fascia with a primary malignant melanoma: effect on recurrence and survival rates. *Surgery* 1982, **92**, 615–618.
6. Breslow A. Thickness, cross-sectional areas and depth of invasion in the prognosis of cutaneous melanoma. *Ann Surg* 1970, **172**, 902–908.
7. Breslow A, Macht SD. Optimal size of resection margin for thin cutaneous melanoma. *Surg Gynecol Obstet* 1977, **145**, 691–692.
8. Ackerman AB, Scheiner AM. How wide and deep is wide and deep enough? A critique of surgical practice in excisions of primary cutaneous malignant melanoma. *Hum Pathol* 1983, **14**, 743–744.
9. Day CL, Mihm MC, Sober AJ, Fitzpatrick TB, Malt RA. Narrower margins for clinical stage I malignant melanoma. *N Engl J Med* 1982, **306**, 479–482.
10. Roses DF, Harris MN, Rigel D, Carrey Z, Friedman R, Kopf AW. Local and in-transit metastases following definitive excision for primary cutaneous malignant melanoma. *Ann Surg* 1983, **198**, 65–69.
11. Kopf AW, Welkovich BA, Frankel RE. Thickness of malignant melanoma: global analysis of related factors. *J Dermatol Surg Oncol* 1987, **13**, 345–419.
12. Marsden JR. Malignant melanoma excision margins (editorial). *Lancet* 1993, **341**, 184.
13. Balch CM, Marshall MU, Karakousis CP, *et al.* Efficacy of 2-cm surgical margins for intermediate-thickness melanomas (1 to 4 mm). Results of a multi-institutional randomized surgical trial. *Ann Surg* 1993, **218**, 362–369.
14. Griffiths RW, Briggs JC. Incidence of locally metastatic (recurrent) cutaneous malignant melanoma following conventional wide margin excisional surgery for invasive clinical stage I tumours: importance of maximal primary tumour thickness. *Br J Surg* 1986, **73**, 349–453.
15. O'Rourke MGE, Altmann CR. Melanoma recurrence after excision. Is a wide margin justified? *Ann Surg* 1993, **217**, 2–5.
16. O'Rourke MGE, Bourke C. Recommended width of excision for primary malignant melanoma. *World J Surg* 1995, **19**, 343–345.

**Acknowledgement**—This study was supported by the Associazione Italiana per la Ricerca sul Cancro (AIRC) with a grant for the year 1995.