Incubation with Con A failed to inhibit the procoagulant activity of the sample. Induction therapy (daunorubicin 80 mg/m^2 for 4 days) achieved a complete remission and complete disappearance of CP from the bone marrow cell extract (Fig. 1)

After the second consolidation cycle (etoposide, cytarabine, daunorubicin) in the presence of multiple cutaneous nodules, the lesions were biopsied and proved to be leukaemic relapses compatible with the M3 subtype. One nodule was utilised to obtain an extract which was tested for the presence of CP, of which a significant amount of CP was detected. 5 months later the patient relapsed in the bone marrow.

Subsequently, another two patients (B and C), have been studied (Fig. 1): in these two cases also the appearance of CP in bone marrow anticipated the relapse by 1–5 months.

Several methods for detection of minimal residual disease have been proposed [7, 8], mainly for acute lymphocytic leukaemia (ALL). Falanga *et al.* [4] recently described the production by ANLL cells of a particular procoagulant substance. This activity disappears upon obtaining complete remission. The presence of this factor in remission BMs could therefore be utilised as a marker of early relapse.

The data presented here show that in 1 ANLL patient the leukaemic relapse was evidenced by the bone marrow CP assay several months before bone marrow relapse and 1 month prior to a peculiar cutaneous recurrence of the disease. No other case of cutaneous localisation of M3 ANLL is available, to our knowledge. Similar data are now available from 2 other patients, with positive CP in the bone marrow anticipating the clinical relapse by 1 and 5 months, respectively (Fig. 1).

If these results are confirmed, this procedure could constitute the first assay for the detection of minimal residual disease in ANLL, a tumour in which molecular biology techniques, such as the detection of monoclonal rearrangement of immunoglobulin or T cell receptor genes, cannot be used.

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Common Errors in Conducting and Reporting Clinical Trials in Non-Hodgkin Lymphomas and Patients' Age

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OLDER ADULTS are at higher risk of developing and dying from malignant tumours than their younger counterparts. However, it is only in recent years that a number of researchers and clinicians have focused their interest on the appropriate clinical management of cancer in the elderly, including non-Hodgkin lymphomas (NHL). It is important to recognise that there are several potential causes of bias in the performance on reporting of trials in NHL, with respect to age. The following are the most common.

Firstly the median age of the patient populations of series reported in the literature is usually between 50–55 years, sometimes between 45–50 years or 55–60 years, but rarely with a median age of more than 60 years. However, one third of NHL patients are more than 70 years and two thirds are over 65. Secondly, recently reported clinical trials where age over 70 is not an exclusion criterion includes the statement that there is no upper age limit for entry into the study. In practice, the number of patients over 70 is small and the median age usually ranges between 50 and 55 years. Therefore, this statement does not mean that the conclusions reached in the studies are applicable to elderly NHL patients.

Thirdly, patients may be grouped, for example, into those younger or older than 60 years, and complete response and survival rates compared. However, the median age of the older patients is usually not reported and hence the conclusion that older age does not influence complete response or survival rate is not acceptable. Fourthly, "age is not a prognostic factor" is another common assertion; however, patients tend to be selected for entry into the study mainly because of their age. Fifthly, conclusions almost never state that the results presented are valid for a patient population of that median age. As a result, the use of the conclusions of the trials in older patients may be associated with an increased percentage of treatment-related toxic deaths.

The quality of reporting of clinical trials in NHL, particularly with regard to age, should be improved.

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