expression in our series of T1–2 laryngeal tumours. Our scoring system was designed to be simplistic in order that inter-observer variation may be minimised. Upstream and downstream regulators in the Cox-2 pathway should be investigated and prospective clinical studies will be required to confirm the importance of Cox-2. The failure rate for laryngeal cancer patients with a stage T1–2 tumour treated with radiotherapy is \( \sim 10\% \), which means that multi centre trials will be required, but this is a significant clinical problem in this subset of patients.

P. Nix

Postgraduate Medical Institute of the University of Hull in association with Hull York Medical School, University of Hull, Hull, HU6 7RX, UK (E-mail: p.a.nix@hull.ac.uk)

References


doi:10.1093/annonc/mdh441

Insurance for independent cancer trials

According to the ICH-GCP [1] and a recent EU directive [2], promoters of multicentre clinical trials should provide an insurance policy for each study, covering damages eventually occurring to enrolled patients because of trial procedures. The cost of policies may be lowered in case a franchise is applied, that is a threshold of indemnity under which the promoter will pay directly for the eventual damage induced to the patient; but the latter is seldom accepted by non-profit promoters because of unforeseeable financial risk.

We collected data on 62 quotations from 12 non-profit Italian promoters of cancer trials [Associazione per la Promozione della Ricerca Clinica—Clinical Trials Promoting Group (APRIC-CTPG); Istituto Oncologico Romagnolo (IOR); Gruppo Oncologico Italiano per la Ricerca Clinica (GOIRC); Gruppo Oncologico Italia Meridionale (GOIM); Gruppo Italiano di Oncologia Geriatrica (GIOGER); Gruppo Oncologico Nord-Ovest (GONO); Dipartimento di Endocrinologia e Oncologia molecolare e Clinica, University Federico II of Naples (DEOMC); Istituto di Ricerche Farmacologiche Mario Negri Institute of Milan (IRFMN); Southern Italy Cooperative Oncology Group (SICOG); Gruppo Italiano per lo studio dei Carcinomi dell’Apparato Digerente (GISCAD); and Società Italiana di Chirurgia Oncologica (SICO)]. Only two insurance companies were interested in issuing such a type of policy without franchise: company A (14 quotations) and company B (22 quotations). With company A, the median cost per patient was 85.50 euros (€) (range 18.00–196.00). A backwards stepwise multiple linear regression analysis revealed that the date of quotation \( (P=0.0002) \), sample size \( (P=0.008) \) and number of study arms \( (P=0.02) \) were independently predictive of cost, and accounted for 88% of its variability. Cost was higher for more recent quotations, smaller sample size and phase II rather than III trials. Among the 22 quotations issued by company B, the median cost per patient was 80.00 € (range 30.00–165.00). Multivariate analysis revealed that only the number of study arms was significantly predictive of cost \( (P=0.0001) \), which was higher with a lower number of study arms, and this variable accounted for 57% of the variability of the cost. Among the quotations from company B, the date of quotation was associated with cost only in the univariate analysis. In Figure 1, the association of cost with date of quotation is graphically displayed for both company A (filled circles, solid line) and company B (open squares, dashed line). These data show that the cost of policies is sharply increasing over time, and this trend can become a serious problem for non-profit promoters of cancer clinical trials. In addition, it seems that there is insufficient competition among companies for insurance of cancer trials with non-profit promoters.

Acknowledgements

The authors thank Fiorella Romano for assistance during data collection and data management. The Clinical Trials Unit of the National Cancer Institute of Naples is partially supported by AIRC (Associazione Italiana per la Ricerca sul Cancro) and CTPG (Clinical Trials Promoting Group). This work was presented as a poster at the Fifth National Congress of Italian Society of Medical Oncology (AIOM).
t(14;18) and bcl-2 should not be used synonymously

In their review on challenging paradigms in lymphoma treatment, Bendandi et al. [1] used the term ‘bcl-2-positive cells’ when they were really talking about cells with translocation t(14;18).

I would like to encourage authors of scientific manuscripts to be strict in their terminology. Names of proteins are increasingly mixed up with genetic terms. In particular, the expression of bcl-2 is often used synonymously with translocation t(14;18) (q32;q21). Many cells transcribe bcl-2, a normal gene coding for the bcl-2 protein regulating apoptosis, not just cells with t(14;18). In fact, in the paper by Huang et al. [2], referenced by the authors, there was no difference in the expression of bcl-2 in the t(14;18)-positive and -negative cases. The chromosomal translocation is the feature identifying the subset of diffuse large B-cell lymphoma with a germinal center gene expression profile, not the expression of the protein bcl-2.

N. Frickhofen*

Dr. Horst-Schmidt-Klinik, Department of Hematology and Oncology, Wiesbaden, Germany (*E-mail: norbert.frickhofen@hsk-wiesbaden.de)

References


do10.1093/annonc/mdh440