European Journal of Cancer, Vol. 34, No. 3, p. 427, 1998

Printed in Great Britain
0959-8049/98 $19.00+0.00

Book Review

PII: S0959-8049(97)10052-1

Breast Cancer: A Psychological Treatment Manual
Editor: Sandra Haber
Publishers: Springer (1997)
ISBN: 1-85343-369-1

A PSYCHOLOGICAL treatment manual has been written for counsellors and psychologists who work with women with breast cancer and their families. It is a comprehensive guide to the emotional, psychological and social issues faced by women with breast cancer and the methods which can be used by a therapist to support them.

The book starts with an excellent description of breast cancer and a thorough, yet simple, description of the treatments and complex treatment options that a woman with breast cancer may face. This section explains how the counsellor or therapist can support the woman in making her choice and also in coping with the physical and emotional effects of treatment.

It moves on to a discussion of the role of the therapist in supporting a breast cancer patient and in facilitating and encouraging communication between the patient and their cancer specialist. This section is very much tailored towards the American health care system and way of life where the role played by therapists is emphasised so much more than is currently the case in Europe.

The chapter on reactions to diagnosis and treatment is very thorough, and that on the emotions which may be experienced when treatment has ended is excellent. The possible effects on all areas of a woman's life are covered in detail and the counsellor or therapist is given tips on the most appropriate therapeutic strategy at each stage of the illness.

The effects of the illness and treatment on others in the patient's life are exceptionally well described and their need for psychological support (which may often go unrecognised) is emphasised. The chapter on the needs of special populations is very American in its wording, but very comprehensive. The book then moves on to the need for support during recurrence and terminal illness and the role and benefits of support groups and group therapy.

There is a chapter on specific therapeutic interventions which the therapist can adopt and indications for their use, and a review of research findings to date into the effectiveness and benefits of psychological support for women with breast cancer.

The final section is a very useful overview of resources for patients and health care professionals in both the U.K. and U.S.A., which includes books and organisations that offer information, counselling and emotional support.

Although written specifically for counsellors and therapists, this book may also be helpful for health professionals who have not received specialist training in oncology and wish to learn more about how to support the women with breast cancer in their care.

D. Coats
Senior Cancer Information Nurse Specialist
Cancer Support Service
cancerBACUP
3 Bath Place
Rivington Street
London EC2A 3JR
U.K.

Received 17 Apr. 1997; accepted 29 May 1997.

European Journal of Cancer, Vol. 34, No. 3, pp. 427–428, 1998

Printed in Great Britain
0959-8049/98 $19.00+0.00

Letters

PII: S0959-8049(97)00375-4

Why Are Patients with Malignant Lymphomas Excluded from Clinical Trials? The Experience of an Oncology Institute in Italy

D. Serraino,[1] V. Zagonel,[2] R. Bordonaro[2] and S. Franceschi[1]

[1]Servizio di Epidemiologia; and [2]Divisione di Oncologia Medica, Centro di Riferimento Oncologico, Via Pedemontana Occ., 33081 Aviano (PN), Italy

IT IS widely recognised that randomised controlled clinical trials provide the only unbiased assessment of treatment efficacy, and that they represent the mainstay through which basic science reaches the bedside. However, the proportion of cancer patients eligible for clinical trials actually enrolled into such studies remains low, particularly for older patients [1]. In the United States, thousands of elderly patients are excluded from clinical trials because Medicare, which pays treatment costs for people over 65 years of age, is unwilling to pay extra costs associated with experimental studies [2]. In the United Kingdom, old age was the only exclusion criterion in nearly 30% of patients with malignant lymphomas excluded from clinical trials between 1981 and 1992 [3].

Correspondence to D. Serraino.
Received 3 Jul. 1997; accepted 21 Jul. 1997.

Table 1. *Distribution of* 115 *patients with lymphomas according to inclusion into clinical trials and selected characteristics: Italy,* 1995

Characteristics	Clinical trials		
	Included ($n=63$) No. (%)	Not included ($n=52$) No. (%)	Total ($n=115$) No. (%)
Age (years)			
≤ 64	50 (79)	35 (67)	85 (74)
≥ 65	13 (21)	17 (33)	30 (26)
Gender			
Male	32 (51)	22 (42)	54 (47)
Female	31 (49)	30 (58)	61 (53)
Type of lymphoma			
Non-Hodgkin's lymphoma	39 (62)	47 (90)	86 (75)
Hodgkin's disease	24 (38)	5 (10)	29 (25)
Stage			
I	9 (14)	18 (35)	27 (23)
II	16 (25)	12 (23)	28 (24)
III	18 (29)	8 (15)	26 (23)
IV	20 (32)	14 (27)	34 (30)
Grade—NHL*			
Low	10 (26)	20 (43)	30 (35)
Intermediate	22 (56)	18 (38)	40 (47)
High	6 (15)	3 (6)	9 (10)
Miscellaneous	1 (3)	6 (13)	7 (8)

*It includes only 86 patients with non-Hodgkin's lymphomas.

We took advantage of an ongoing study on the economic evaluation of extra costs attributable to phase II and phase III trials among patients with non-Hodgkin's lymphomas (NHL) and Hodgkin's disease (HD) to quantify the proportion of lymphoma patients who were actually enrolled into clinical trials at Aviano Cancer Centre, North east Italy, one of the six public National Cancer Institutes. Data regarding all newly diagnosed patients with NHL and HD, and discharged in the first study year (i.e. 1995), are herein reported.

Table 1 shows the characteristics of the 115 patients with malignant lymphomas under investigation, according to inclusion in clinical trials. Among these patients, 52 (45%) were not included in clinical trials and, therefore, underwent standard treatments. Exclusion from trials was significantly more frequent among patients with NHL (55%) than among those with HD (17%) ($\chi^2_1 = 10.79$, $P = 0.001$). Patients not included in trials tended to be older and to have more favourable stages of disease than those included, but these differences (Table 1) were not statistically significant. Patients with low-grade NHL or with miscellaneous histologies were less frequently included in clinical trials than patients with intermediate- or high-grade disease (Table 1) (χ^2_1 for trend $= 4.41$, $P = 0.04$).

As concerns individual's exclusion criteria from clinical trials conducted at Aviano Cancer Centre in 1995, 20 (39%) out of the 52 patients were not included in trials because of stage and 12 (23%) because of histology, since the concurrent trials were chiefly targeted to advanced diseases. 12 patients (23%) could not be enrolled because they lived too far away from the Institute, while 8 patients (15%) were excluded because of old age (i.e. more than 69 years). Of the 63 patients included in trials, 12 (19%) entered phase II and 51 (81%) phase III trials.

Although the present analysis was based on a small number of patients, and restricted to 1 year's activity, our findings are consistent with those reported by the Sheffield Lymphoma Group, where 55% of patients with malignant lymphomas were not entered into clinical trials [3]. The majority of those patients were excluded because of medical conditions (37%) or age (28%), with only 7% not enrolled due to the clinicians' decision [3].

Our results confirm that even in research-oriented clinical institutions, nearly half the patients with malignant lymphomas are not entered into clinical trials. In contrast, we have not documented exclusions attributable to the clinicians' decision, while old age represented, at our Centre, a less frequent exclusion criterion compared to the Sheffield Lymphoma Group, since a major effort to involve elderly patients in clinical trials has been made for some years [4].

Finally, our results point to a particular lack of clinical trials on well-differentiated lymphomas, for which traditional cytotoxic anticancer agents work less and new approaches are most needed [5].

1. Kenney BJ. Needed clinical trials for older patients. *J Clin Oncol* 1991, **9**, 718–720.
2. Culliton BJ. Easier access to clinical trials. *Nature Med* 1997, **4**, 369.
3. Hancock BW, Aitken M, Radstone C, Vaughan Hudson G. Why don't cancer patients get entered into clinical trials? Experience of the Sheffield Lymphoma Group's collaboration in British National Lymphoma Investigation studies. *BMJ* 1997, **314**, 36–37.
4. Fentiman I, Trelli U, Monfardini S, *et al.* Cancer in the elderly: why so badly treated? *Lancet* 1990, **28**, 1020–1022.
5. Astrow AB. Rethinking cancer. *Lancet* 1994, **343**, 494–495.

Acknowledgements—This study was conducted within the framework of the FSN, Finanziamento Ricerca Finalizzata, 1994, Ministero della Sanità, Rome, Italy.

European Journal of Cancer, Vol. 34, No. 3, pp. 428–429, 1998

Printed in Great Britain
0959-8049/98 $19.00+0.00

PII: S0959-8049(97)10013-2

Human Transplacental Passage of the Retinoid Fenretinide (4HPR)

F. Formelli,[1] G. De Palo,[1] A. Costa[2] and U. Veronesi[2]

[1]Istituto Nazionale Tumori, 20133 Milan, Italy; and [2]European Institute of Oncology, Milan, Italy

WE INVESTIGATED whether 4HPR, a synthetic retinoid currently under investigation for the prevention of epithelial

Correspondence to F. Formelli.
Received 17 Jul. 1997; accepted 29 Jul. 1997.