Eur J Cancer Clin Oncol, Vol. 19, No. 3, pp. 179–185, 1983
Printed in Great Britain.

0277-5379/83/020179-07$03.00/0

Care of Cancer Patients in Thirty-one Italian General Hospitals. Methodological Aspects and General Findings*

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Abstract—*A large sample of cancer patients was reviewed over a two-year period* (1978–1979) *in* 31 *general and community hospitals representing five Italian regions, differing in terms of health care organization. Two thousand four hundred and six patients had breast cancer,* 1692 *lung cancer,* 303 *non-Hodgkin's lymphomas,* 277 *ovarian cancer and* 235 *Hodgkin's lymphoma. Relevant information was collected from medical records through specific pre-standardized and tested forms. The paper discusses the results obtained with respect to* (*a*) *general descriptive data of the population*; (*b*) *completeness and reliability of recorded data* (*e.g. staging, histological classification, therapy*); *and* (*c*) *accuracy and completeness of the follow-up. Consistency of the information obtained on selected items with published series of patients suggests that this methodology is worth a wider testing as a simple, inexpensive tool for routinely monitoring the care of cancer patients and the impact on it of organizational and educational interventions.*

INTRODUCTION

OVER THE last few years, evaluation of the quality of diagnostic and therapeutic care has become one of the most controversial and fastest growing fields of research in many areas of medicine. Problems of cost assessment and containment are in most cases the motives for such investigations [1, 2]. In addition, however, questions about the clinical implications of health delivery systems on the outcome of therapeutic and diagnostic procedures and on the often substantial differences observed between results in a controlled environment and in large-scale routine practice are becoming more explicit and attract increasing attention [3–5].

The area of cancer care is an obvious, though difficult, candidate for specific interest on the grounds of both the lines of motivation given above. The importance of the issue has been stressed in recent studies, where these problems have proved central for any tentative assessment of the value of intervening on 'curable' and 'incurable' tumours [6–14]. Research for appropriate methods of obtaining reliable and interpretable data can in itself be taken as a priority task because of the manifold difficulties of the problem.

As the first part of a large project addressing the question of the relationship between the quality and outcome of care, the care given to cancer patients in a large sample of non-research-oriented Italian hospitals was monitored following a relatively simple, hence potentially widely applicable, design.

This paper reports main general findings concerning care and discusses the methodology adopted in data collection, its reliability and interpretation.

MATERIALS AND METHODS

Patients

Five types of cancer representing opposite degrees of incidence and curability have been studied in groups of hospitals covering defined areas in Northern, Central and Southern Italy, where there are quantitative and qualitative differences in health care structures. In each

Accepted 7 May 1982.
*This study was supported by a contract of the Italian National Research Council, Progetto Finalizzato 'Controllo delle Crescita Neoplastica' Contratto No. 80.01660.96 and by the Italian Association for Cancer Research.
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hospital group different levels of organization were represented to give the overall following distribution: three hospitals with fully equipped oncological services, including radiotherapy; ten hospitals with oncological wards (and some ambulatory facilities); eighteen general and community hospitals with no specific oncological services. Cases were identified through hospital discharge registries and their records were screened with the agreement of the medical staff in charge by medically qualified investigators, trained and tested for comparative reliability in transferring data from medical records to specific forms, which included pre-coded items and free-text reporting.

Of the 35 selected hospitals, 31 participated in the study, with the agreement of all radiotherapy and oncological services and 94% acceptance of other departments (medicine, surgery, gynaecology).

Two groups of patients were analysed to allow for comparative assessment of the accuracy of data reporting and retrieving from past and current medical records respectively: group A includes 3838 patients retrieved retrospectively to describe all confirmed cancer cases seen over a two-year period (1978–1979); group B includes 1075 patients collected prospectively to describe only cases diagnosed in the group of hospitals over a ten-month period (March–December 1979).

Of the considered cases, 38 patients in group A and 10 in group B were excluded from the study because of secondary neoplasm, and differences between the diagnosis in the hospital registries and in the patients charts.

The following items of information were included in the survey: general identification data; clinical history preceding and leading to the index hospital admission; diagnostic (staging) and therapeutic procedures in hospital; variables selected as indicators of the quality of care (accuracy of follow-up, documentation of side-effects). The same data were collected for patients in groups A and B, with the exception of those referring to clinical history preceding and leading to the index hospital admission, which had to provide for group A the assessment of clinical history (time of first diagnosis, criteria and quality of follow-up) and for group B the cause of admission, admission diagnosis, examinations before and during admission and leading to actual diagnosis. The following sets of diagnostic examinations were established as a reference standard for evaluating the actual performance of different hospitals: (in the following as well as in the Tables, tumours are listed according to their degree of curability) Hodgkin's: haematological/biochemical data–chest X-ray–nodal biopsy–bone marrow biopsy and bone marrow aspirate–lymphography (in selected cases, laparatomy with splenoctomy); breast: chest X-ray–mammography (or xeromammography)–node pathology–bone scan (or skeletal X-ray); non-Hodgkin's; haematological/biochemical data–chest X-ray–nodal biopsy–bone marrow biopsy and bone marrow aspirate–skeletal X-ray–urography–lymphography (in selected cases, laparotomy with splenectomy); ovary: chest X-ray–laparotomy with intraoperatory biopsies–peritoneal washing (or ascitic fluid) examination–urography; lung: chest X-ray–tomography–bronchoscopy (with biopsy) and/or sputum cytology–bone scan (or sketal X-ray).

The main data were recorded centrally and stored in an automated data system after a complete check of their consistency.

RESULTS

A total of 235 patients with Hodgkin's lymphoma (aged from 11 to 85, median 45), 2406 with breast cancer (aged from 25 to 90, median 59), 303 with non-Hodgkin's lymphomas (aged from 14 to 90, median 64), 277 with ovarian cancer (aged from 20 to 84, median 58) and 1692 with lung cancer (aged from 30 to 88, median 65) were identified for the study. For each type of tumour, results of the retrospective and of the prospective group are presented separately as A and B. Tables 1 and 2 present the two populations according to the classification adopted for their description and to their distribution in various stages.

A relatively (breast Ca and lymphomas) and substantially (lung and ovary Ca) low proportion of cases were described by standard classification systems. Only for an even lower percentage of cases (overall 33% for group A and 35% for group B) could we find any statement of the stage. Lung Ca is the least documented, followed by ovary Ca in both groups A and B. Hodgkin's lymphoma and breast Ca are the best documented, though a large proportion cannot be attributed to any defined clinical stage. The availability of histological classification is reported in Table 3. Group B fares consistently better than group A, though the differences are not particularly large except for breast Ca and Hodgkin's lymphoma, where standard classification was used in 53 and 79%, and 71 and 93% respectively of the cases in the two groups.

A detailed description of the therapeutic

Table 1. Use of standardized staging classification

	Group	Patients (No.)	Not classifiable (%)	Standard classification (%)	Lymph nodal status (%)*
Hodgkin's	A	207	34	65	1
	B	28	46	54	—
Breast	A	1934	39	42	19
	B	472	21	57	22
Non-Hodgkin's	A	251	57	43	—
	B	52	63	37	—
Ovary	A	209	67	29	4
	B	68	71	23	6
Lung	A	1237	76	13	11
	B	455	74	16	10
Total	A	3838	54	33	13
	B	1075	49	37	14

*For Hodgkin's and non-Hodgkin's lymphomas this category refers to the documentation of nodal/extranodal involvement.

Table 2. Staging documentation

	Patients			Distribution of documented cases			
	Group	No.	Data availability (%)	Stage I (%)	Stage II (%)	Stage III (%)	Stage IV (%)
Hodgkin's	A	207	65	6	17	53	24
	B	28	54	6	27	40	27
Breast	A	1934	41	9	44	37	10
	B	472	55	13	44	36	7
Non-Hodgkin's	A	251	43	6	10	31	53
	B	52	37	5	11	27	58
Ovary	A	209	29	10	13	48	30
	B	68	24	19	6	44	31
Lung	A	1237	12	10	11	45	33
	B	455	15	3	24	49	24
Total	A	3838	33				
	B	1075	35				

Table 3. Availability and type of histological classification

	Group	Patients (No.)	Not classifiable (%)	Standard* (%)	Other (%)
Hodgkin's	A	207	28	71	1
	B	28	7	93	—
Breast	A	1934	38	53	9
	B	472	12	79	9
Non-Hodgkin's†	A	251	12	61	27
	B	52	8	71	21
Ovary	A	209	24	76	—
	B	68	16	84	—
Lung	A	1237	40	51	9
	B	455	28	62	10
Total	A	3838	36	55	9
	B	1075	19	72	9

*The following standard classifications were adopted: Hodgkin's, breast, ovary, lung = WHO. Non-Hodgkin's = Rappaport.

†The high frequency of 'other' may possibly arise from the transition from the old but codified Rappaport classification to other systems.

single and combined procedures adopted for each tumour is offered in Table 4 (data regarding endocrine therapy are not reported because they relate only to breast Ca). Among the side-effects, nausea and vomiting, leucopenia, alopecia, thrombocytopenia and paresthesias, in decreasing order, are the most frequently and regularly reported in group A (13, 46 and 54% for patients treated with radiotherapy, chemotherapy and the two combined respectively) and B (12, 38 and 56%); other side-effects are reported much more rarely. The main aim of Table 5 is to compare the patients who at the end of the two periods of observation were still in or lost to follow-up. With the possible exception of Hodgkin's and non-Hodgkin's lymphomas (though the figures are very low), there do not appear to be substantial differences in the retrospective vs the prospective sample population. A larger proportion of those lost to follow-up appears in the two larger groups of patients, lung Ca and breast Ca.

According to the study design, only group B patients could be considered with respect to diagnostic procedures. The analysis is reported in Fig. 1 and in Tables 6 and 7. Pre-hospital investigations, mainly clinical and instrumental, play a major role in the formulation of diagnosis (Fig. 1). A more detailed analysis shows that diagnosis leading to hospital admission had only to be completed in 60% or confirmed in 13% of patients; 10% were admitted for symptoms not related to cancer, while for 17% data were not available on admission.

The interval between the first report of symptoms and hospital admission (Table 6) is longer than one year in only a small percentage of patients. The clinical relevance of delayed diagnosis should be discussed separately for each tumour, as the significance of 25% of breast Ca patients coming to diagnosis more than 6 months after the first symptoms is clearly different from comparable percentages found for other tumours. In relation to the pre-defined 'package' of diagnostic procedures, the frequency of cases where they were fully executed in hospital appears to be very low: 2% ovarian cancer, 4% non-Hodgkin's lymphomas, 7% Hodgkin's lymphoma and breast cancer, and 8% lung cancer. For various tumours only some of the tests were made, according to criteria which varied in the different hospitals and in single patients. The most frequent patterns included: four tests for Hodgkin's lymphoma (in 36% of this group of patients), three tests for breast Ca (32%), lung Ca (43%) and non-Hodgkin's (35%), and two tests for the ovary (35%).

Table 4. Distribution of single and combined therapeutic procedures

	Group	Patients (No.)	Surgery* (%)	Radiotherapy (%)	Chemotherapy (%)	Surgery + radiotherapy (%)	Surgery + chemotherapy (%)	Radiotherapy + chemotherapy (%)	Surgery + radiotherapy + chemotherapy (%)
Hodgkin's	A	207	13	1	9	9	31	4	31
	B	28	32	—	11	4	46	—	7
Breast	A	1934	24	1	4	18	30	1	20
	B	472	49	1	2	14	21	—	6
Non-Hodgkin's	A	251	8	1	11	3	45	4	25
	B	52	10	—	13	2	52	6	13
Ovary	A	209	13	1	17	11	36	2	12
	B	68	18	2	19	4	38	2	7
Lung	A	1297	6	12	32	3	6	15	3
	B	455	6	10	31	1	3	11	2

*Surgery for Hodgkin's and non-Hodgkin's lymphomas refers mainly to diagnostic procedures.

Table 5. Distribution of patients according to follow-up situation at the end of the observation period

	Group	Patients (No.)	Lost (%)	In follow-up: The same hospital (%)	In follow-up: Transferred (%)	In follow-up: Dead (%)
Hodgkin's	A	207	32	41	17	10
	B	28	18	54	25	3
Breast	A	1934	40	48	2	10
	B	472	46	51	2	1
Non-Hodgkin's	A	251	32	40	10	17
	B	52	19	54	15	12
Ovary	A	209	37	34	9	20
	B	68	32	47	12	9
Lung	A	1237	44	13	5	38
	B	455	50	23	11	16
Total	A	3838	41	35	4	20
	B	1075	45	39	8	8

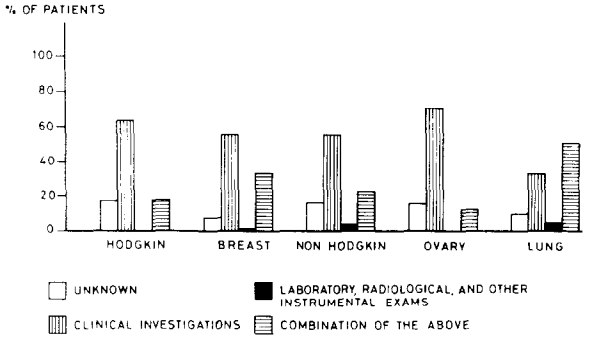

Fig. 1. Diagnostic procedures before hospitalization—Group B.

DISCUSSION

Bearing in mind the intrinsic limitations of reviews based on medical records, and in line with the objectives of the study, two main questions arise in commenting on the results: (a) how far did design and methodology adopted produce reliable information and to what extent can they be considered for general use in extensive programs for monitoring cancer treatment? and (b) what kind of hospital care is readily available to cancer patients within their area of residence, and how is this care related to pre-set quality standards?

The two differently recruited populations, A and B, can be considered as a continuum for the purpose of quality of care assessment as they were consistent as regards data about stage, side-effects reporting, degree of follow-up and therapeutic choices, at least for lung Ca and ovary Ca, for which the different observation periods do not influence the possibility of applying the full or partial sequence of therapeutic procedures. Moreover, patients in group B compare well as regards their distribution by age within each tumour with figures from the Regione Lombardia cancer registry [15], and as regards the frequency of histological and cytological tests found in our hospital group (Table 3) with cancer registries

Table 6. Lag time between first symptoms and first hospital admission–Group B [No. (%)]

	Total	Data not available	≤ 1 month	2–6 months	7–12 months	> 1 yr
Hodgkin's	28	2	6	14	5	1
		(7)	(21)	(50)	(18)	(4)
Breast	472	64	130	162	70	46
		(14)	(27)	(34)	(15)	(10)
Non-Hodgkin's	52	11	11	18	9	3
		(21)	(21)	(35)	(17)	(6)
Ovary	68	17	10	28	11	2
		(25)	(15)	(41)	(16)	(3)
Lung	455	75	160	142	51	27
		(17)	(35)	(31)	(11)	(6)
Total	1075	169	317	364	146	79
		(16)	(29)	(34)	(14)	(7)

Table 7. Histocytological confirmation in male (M) and female (F) group B patients vs various tumour registries (% of all cases)

	Group B		Birmingham (U.K.)		Connecticut (U.S.A.)		Varese (Italy)	
	M	F	M	F	M	F	M	F
Hodgkin's	90	100	97	94	98	97	100	100
Breast	75	88	91	83	98	96	83	88
Non-Hodgkin's*	94	90	96	95	97	98	98	93
Ovary	—	84	—	87	—	96	—	88
Lung	73	68	50	52	84	85	75	63

*Registries in Birmingham and Connecticut include only category 200 VIII I.C.D. (lympho and reticulosarcomas), but not category 202 VIII I.C.D. (other forms of lymphoma), which is included in the Varese Registry and in Group B.

from three different countries [16] (Table 7). These checks suggest that selection of the cases was not particularly biased in our series. The assumption is further strengthened by the few other studies dealing with the same issues for different tumours [17–21], which present results surprisingly similar to ours in general terms. On the assumption that data reported in medical records do represent facts, with no substantial under or mis-reporting, question (b) can now be addressed more confidently. The main findings of the study, needing no extensive comments, are clear from the percentages reported in the tables, particularly with respect to the use of standardized classification (Table 1), the largely unsatisfactory completeness of staging (Table 2) and the substantial proportion of patients lost to follow-up (Table 5).

Besides indicating how care is organized in hospitals, the three variables suggest the very poor probability of patients being followed properly by other hospitals in the absence of documentation of previous history.

The situation does not seem better with respect to the quality of therapeutic care, at least as can be evaluated from the quantity and quality of recorded data. Preliminary analysis of data summarized in Table 4 shows that chemotherapeutic protocols are not fully documented (e.g. cycles or dosages not reported) in around one-third of the cases (29% in group A and 36% in group B); 51% of group A and 42% of group B patients failed to complete the treatment schedule without any documented motivation. For 49% of radiotherapeutic treatments in group A and 30% in group B no information is reported on the type and dosage of radiation. The interest of such 'negative' indicators is enhanced by the findings in Table 7, suggesting that our sample is probably not too far removed from other situations with respect to at least one of the chosen indicators.

One last comment seems warranted on the diagnostic pathway described for group B. The key role of pre-hospital care is stressed by Fig. 1, and Table 6 suggests that major improvements could be made to ensure earlier referral and diagnosis of some patients (mainly breast Ca) following the appearance of first symptoms.

The apparently random and partial selection of diagnostic procedures established for research protocols poses important questions about the feasibility and the yield of full-scale examinations in routine hospital practice.

As a measure of the quality of cancer care available to defined populations within a country, the data presented are highly informative despite their limitations. They are even more challenging as they pose basic questions likely to be valid outside the Italian context [22–25]. Patterns of care in single tumours and the difference in performance between various centres will be analysed more specifically in further papers, and the following questions remain to be answered: (a) what is the relationship, if any, between accuracy and completeness of data reporting and clinical outcome? (b) what is the minimal acceptable burden of procedures in general hospital practice (outside research environments) to assure acceptable results? and (c) are needs the same for 'more-curable' and 'lesscurable' tumours.

No answer to such questions is likely from *ad hoc* studies, unavoidably reflecting limited situations and whose general implications are all too easily amenable to criticism on various grounds. A monitoring program of clinical procedures based on representative network(s) of health care structures and using simple and inexpensive tools seems a realistic working hypothesis consistent with the general aims of the larger national project "Control of Neoplastic Growth" (from basic research to controlled clinical trials). This was the framework

in which the present study was planned and conducted.

Acknowledgements—Regional coordination and local data collection: Cecere Marino, Ferrari Domenico, Franchin Gianni, Giomi Saverio, Martinelli Ulrico, Piccioli Ilde, Roila Fausto, Talamini Renato, Tonato Maurizio.

Clinicians from the following hospitals made this study possible through their help in data retrieval: Arezzo, Avellino, Carrara, Chiavenna, Città di Castello, Como, Cuggiono, Foligno, Gorizia, Grosseto, Gualdo Tadino, Lecco, Legnano, Lucca, Magenta, Morbegno, Monfalcone, Palmanova, Perugia, Pistoia, Pontedera, Pordenone, Rho, Sacile, S. Vito al Tagliamento, Salerno, Sondalo, Sondrio, Tirano, Todi, Val di Chiana.

We thank Anna Mancini for the skillful help in preparing the manuscript, Judy Baggott for the revision of the English text and Graziella Scalvini for preparation of the bibliography.

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