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Original Paper

Evaluation of the Informed Consent Procedure in Cancer Patients Candidate to Immunotherapy

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By addressing questionnaires to 24 cancer patients candidate to immunotherapy, we evaluated both the effects and the effectiveness of the medical information provided to the patient on their knowledge of the disease and the treatment. Most patients had correctly understood the information but 69% stated that they had been unable to ask all the questions they wished, and 62% required additional information. Most patients admitted to being emotionally distressed throughout the interview. These results are not significantly different from those obtained in patients candidate to new chemotherapy agents, but show that important improvements in the informed consent procedure are required.

Key words: informed consent, cancer, immunotherapy
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INTRODUCTION

CONTROLLED THERAPEUTIC trials represent an agreement between physicians and patients in order to test new modalities of treatment which require informed consent [1, 2]. This procedure theoretically warrants that both the patient and the investigator share the decision of completing a specific treatment with the knowledge of its potential advantages and side-effects, as required by the Helsinki declaration.

Few evaluations of this procedure have yet been reported by European oncologists, especially in France where written informed consent has been legally required only since 1988 [3]. We initiated a new therapeutic programme based on interleukin 2 (IL-2) therapy and our patients, treated within phase II non-randomised trials, had to consent to treatment in writing [4]. We evaluated the effects of the information given to them prior to consent.

PATIENTS AND METHODS

24 adult patients, 15 with metastatic renal carcinoma, 9 with metastatic melanoma (15 men, 9 women, median age 56) were asked to respond to a written questionnaire. All 24 patients were eligible to receive IL-2 within specific phase II trials and all accepted this treatment.

The patients were given the following explanations:

-their primitive tumour was a renal tumour or a melanoma and had been previously removed; they now suffered from several distant recurrences of their disease which cannot be removed by surgery or other local procedure. The sites of the different involved organs were revealed to the patients;
-they had the opportunity to receive a new type of treatment with IL-2. Although successful treatment of their disease was not guaranteed, this treatment would be administered in this hope.
-the toxic effects of the treatment were discussed in detail and the exact treatment schedule was explained.

Typeset information documents were given to the patients, together with the informed consent form. When the interview was over, the clinical nurse asked them if they would complete a questionnaire regarding the interview and the information they had just received. In addition, a questionnaire was also addressed to the physicians.

RESULTS

Medical interview procedure

24 patients participated in this study. The mean duration of the medical interview was 25 min (range 15–45) and 73% (16/22) patients found it sufficient (Table 1). 20 (87%) out of 23 patients estimated they had obtained responses to their questions, but 7/23 (30%) remarked that the interview failed to address some of their questions (see Table 1 for details).

Patients gave the following reasons for not asking all of their questions: they did not have enough time, or felt uncomfortable or too anxious. The questions they could not address concerned the percentage of treatment success, the possible evolution of the disease, the side-effects of the treatment, or previous results

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Table 1. Evaluation of the interview process by the patients

Questions	Yes	No	Unanswered
Duration of visit is sufficient?	16	6	2
Strangers made you feel uncomfortable?	2	22	-
Doctor's responses were appropriate?	20	3	1
Could you ask all the questions you had?	16	7	1
How did you feel after the visit?			
-reassured	9	12	3
-informed	16	5	3
-anxious	15	7	2
-emotionally upset	20	1	3
-depressed	4	18	2
-surprised	11	9	4
-satisfied	20	2	2

obtained with this investigational drug. Most patients mentioned they were emotionally upset (20/21) or anxious (15/22), and only 9/22 felt reassured (Table 1).

Informed consent

Patients' responses about the informed consent procedure are shown in Table 2. Most patients (20/24) indicated that before the interview, they knew the diagnosis of their disease, including its severity, but less than half (10/24) had heard about IL-2 therapy. After the interview, all patients said they knew their diagnosis as well as the treatment's schedule and toxicity. Notably, 19/21 patients stated they were aware of the uncertainty of the treatment success and 15/24 patients mentioned a need for more information. All patients asserted they knew they were participating in a therapeutic trial.

Table 2. Evaluation of the information process

Questions	Yes	No	Unanswered
Prior to the interview			
Did you understand the diagnosis of your disease?	20	4	-
Did you understand the potential severity of your disease?	20	3	1
Had you heard about IL-2?	10	14	-
After the interview			
Do you understand the diagnosis of your disease?	24	-	-
Its potential severity?	23	-	1
Do you know about IL-2?	24	-	-
Are you familiar with your treatment plan?	24	-	-
Are you aware of the treatment's potential side-effects?	24	-	-
Are you aware of the uncertainty of the success?	19	2	3
Do you need additional information?	15	9	-
If yes,			
-about your disease,	15	6	3
now	6		
later	9		
-about your treatment,	14	8	2
now	5		
later	9		
Are you aware of your participation in a therapeutic trial?	24	-	-

The physicians' evaluation of their patients' knowledge and understanding was consistent with the responses provided by the patients but was generally underestimated (data not shown). However, responses regarding diagnosis of the disease and adverse effects of treatment (100% versus 100% and 100% versus 95%) coincided.

DISCUSSION

Although the patients in this study were subjected to a completely new form of cancer treatment (i.e. immunotherapy), our results do not appear to differ greatly from those obtained from patients receiving a more conventional, but still experimental anticancer drug [5]. Consistent with the few previous studies investigating this subject, the physicians underestimated to a certain degree the knowledge and understanding of the patients [1, 5].

Patients seemed to understand correctly the information given, although patients found the interview too short, 15 patients wished to obtain more information, and 7 claimed to have been unable to ask all the questions they wanted. Interestingly, some questions that the patients could not ask concerned critical issues such as percentages of treatment success or evolution of the disease; reasons for not asking these questions were that the patients were "too anxious" or "felt uncomfortable" and only 9/22 felt reassured by the medical interview. These remarks indicate that patients feared pejorative responses, and were in a state of anxiety.

Two major points emerge from these results: patients receiving a great deal of information in a short period of time are not in the best condition to make decisions, and cancer patients undergoing an informed consent process have an acute need of psychological support. Even if the additional stress caused to patients by the informed consent procedure is controversial, some authors recognise that, since many critical issues are addressed, most patients reach an abnormal emotional state which causes bias in the decision-making process [2, 6–9]. All studies report a significant percentage of patients who cannot recall or understand all the information they were given [10].

For these reasons, we must improve our procedures, for example, allow an extended period of time to elapse before patients make their decision, and provide them with greater opportunities to ask questions indirectly. The role of the clinical nurse, who unfortunately remains unrecognised in title or position in France, appears particularly important during this critical period.

Informed consent theoretically implies that physicians give complete and non-oriented information to their patients to allow them to make their own decisions [11]. These statements are particularly difficult to fulfil in cancer patients who are frightened by the disease and who seek sympathy and reassurance [6, 7, 12]. For these reasons, the effectiveness and the psychological effects of this procedure require careful evaluation with the same goal of improvement as in actual cancer treatments. Studies in this field must be encouraged and developed.

1. Burchell HB. Vicissitudes in clinical trial research. Subjects, participants, patients. *Cont Clin Trials* 1992, **13**, 185–189.
2. Eardley A, Cribb A, Pendleton L. Ethical issues in psychological research among patients with cancer. *Eur J Cancer* 1991, **27**, 166–169.

3. Protection des personnes se prêtant à des recherches biomédicales. Loi n° 88–1138 du 20/12/88. *Journal Officiel de la République Française* 22/12/88.
4. Négrier S, Mercatello A, Coronel B, *et al.* IL2 therapy, report on 129 patients and 3 different schedules. In Staehler G, Pomer S, eds. *Contemporary Research on Renal Cell Carcinoma. Basic and Clinical Developments*. Bangalore, India, Scientific Publishing Services, 1994, 56–62.
5. Penman DT, Holland JC, Bahna GF, *et al.* Informed consent for investigational chemotherapy: patients' and physicians' perception. *J Clin Oncol* 1984, **2**, 849–855.
6. Annas GJ. Informed consent, cancer and truth in prognosis. *N Engl J Med* 1994, **330**, 223–225.
7. Sutherland HJ, Lockwood G, Till JE. Are we getting informed consent from patients with cancer? *J R Soc Med* 1990, **83**, 439–443.
8. Redelmeier DA, Rozin P, Kahneman D. Understanding patients' decisions. Cognitive and emotional perspectives. *J Am Med Assoc* 1993, **270**, 72–76.
9. Simes RJ, Tattersall MHN, Coates AS, Raghavan D, Solomon HJ, Smartt H. Randomised comparison of procedures for obtaining informed consent in clinical trials of treatment for cancer. *Br Med J* 1986, **293**, 1065–1068.
10. Cassileth BR, Zupkis RV, Sutton-Smith K, March V. Informed consent, why are its goals imperfectly realized? *N Engl J Med* 1980, **302**, 896–900.
11. de Raeve L. Informed consent and living wills. *Eur J Cancer Care* 1993, **2**, 150–156.
12. Meisel A, Roth LH. What we do and do not know about informed consent. *Am Med Assoc* 1981, **246**, 2473–2477.