Journal of Radiotherapy in Practice

Journal of Radiotherapy in Practice 2001
2, 169–173

Original Article

The informed consent procedure from the patients' perspective. An observational study

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Abstracts

From April 1997 until September 1998 an observational study was performed with respect to the quality of the "informed consent procedure concerning patients who were candidates to participate in the EORTC-trial 10925/22922. This phase-III trial deals with the question of whether irradiation of the internal mammary chain together with the ipsilateral supraclavicular chain leads to a better survival in patients with operable breast cancer. Patients with either medially located primary tumours or with (ipsilateral) axillary lymph node metastases were eligible for participation. Patients were, in our study, considered eligible if they were candidates for participation in the above mentioned EORTC-trial. After they had agreed to participate in the informed consent study, 2 radiological technologists interviewed 51 patients. It appeared that patients were well aware of it) the important characteristics of their disease; ii) the purpose of the treatment; iii) the fact that they were candidates for participation in a phase-III trial; iv) the fact that randomisation had taken place (for the participants). According to the answers of the patients it appeared that the quality of the information, as given by their physician, was good. Further attention needs to be given to the time allocated to the patients to consider their participation in the trial. The quality of the informed consent procedure could be measured adequately. Preferably this type of analysis should be performed at the start of a (large) trial. By doing so, the quality of the informed consent procedure can be evaluated and eventually the quality of the procedure can be improved.

Keywords

informed consent, clinical trial, breast radiotherapy, quality of information

INTRODUCTION

Investigators will, apart from bearing scientific responsibility, be confronted with ethical dilemma's concerning, amongst others, the justification and design of the trial, subject selection and informed consent. The ethical principles of biomedical research should be observed in accordance with a consistent moral code. The moral code of Good Clinical Practice (GCP) was developed in order to rule out inconsistencies.[1,2] The principles of GCP are the protection of the rights of human subjects, integrity and reproducibility of data, and transparency of conduct. According to the rules of GCP patients can only agree to participate in a clinical trial after he or she has been properly informed, the information is understood and he or she is able to decide whether or not to participate in such a trial.

From April 1997 until September 1998 a study was performed with respect to the quality of the informed consent procedure for patients who were candidates to participate in the EORTC trial 10925/22922. This phase-III trial deals with the

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https://doi.org/10.1017/S1460396900000261 Published online by Cambridge University Press

question of whether irradiation of the internal mammary chain together with the ipsilateral supraclavicular chain of lymph nodes patients with operable breast cancer leads to a better survival. Patients with either medially located primary tumours or with (ipsilateral) axillary lymph node metastases were eligible for participation. This phase-III study was initiated in 1997 and by January 2001 more than 2.100 patients were randomised, with an accrual of 124 in Utrecht.

Patients who refused participation in the EORTC-trial (group R) and patients who had agreed to participate in the EORTC-trial (group P) were candidates to participate in our study. The purpose of our study was to investigate the quality of information for the consent procedure. Furthermore we investigated whether patients found themselves able to make a proper decision. Two radiological technologists interviewed patients after they had agreed to participate in the informed consent study.

MATERIAL AND METHODS

We asked 73 patients to participate in this observational study. Ultimately, however, 22 of them refused to participate. Hence, the study population consisted of 51 women, 27 of them had agreed to participate (group P) and 24 had refused to participate in the above mentioned EORTC trial (group R), respectively. After they had agreed to participate in our informed consent study, 2 radiological technologists interviewed all 51 patients. Interviews took place in the first week of the irradiation, because sick effects due to the irradiation were not to be expected.

The questionnaire consisted of 5 social demographic questions and 38 open questions. Questions concerned specific aspects of the treatment, including knowledge about their disease, knowledge about their prognosis and finally, knowledge about specific aspects of the irradiation. Moreover, patients were asked whether they were satisfied with the information

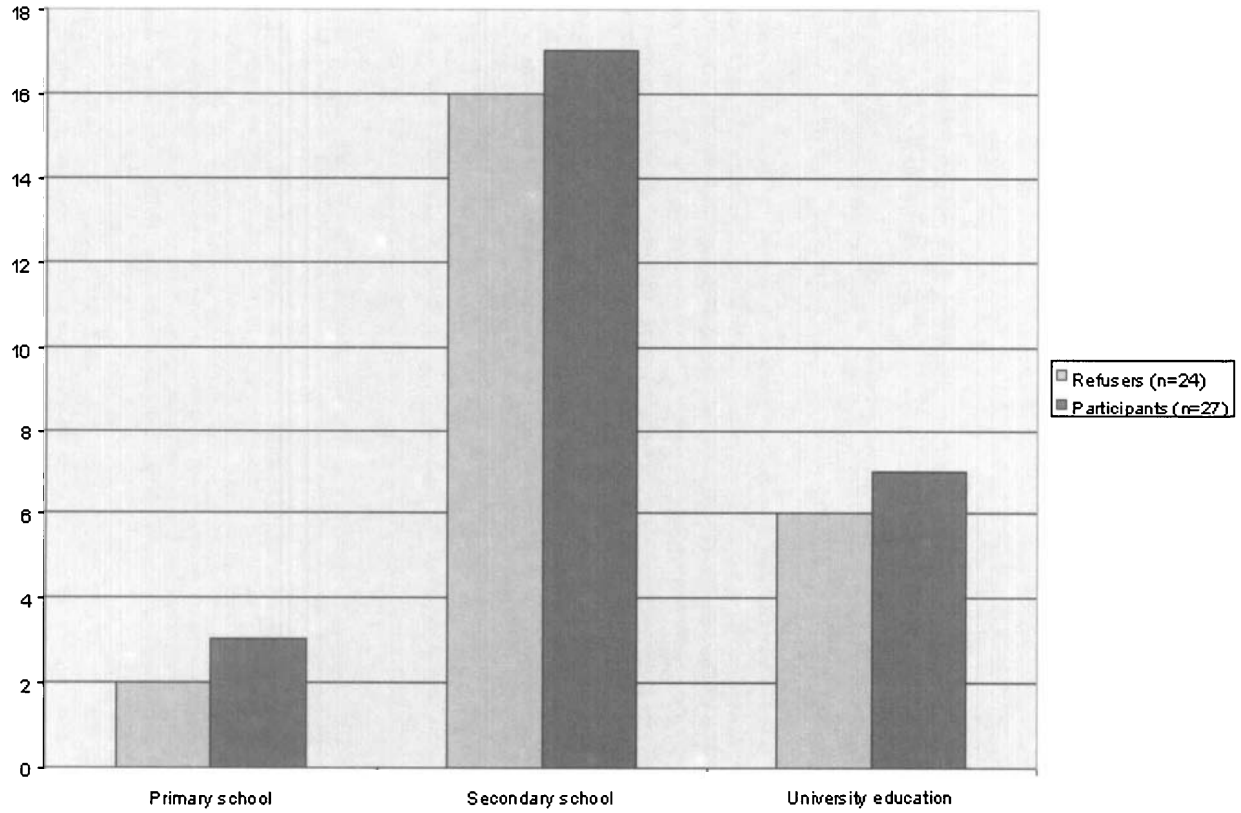

Figure 1. The level of education.

https://doi.org/10.1017/S1460396900000261 Published online by Cambridge University Press

as given, with respect to the trial. The mean duration of the interviews was 30 minutes.

RESULTS

Age varied from 36 till 74 years and the mean age for both groups was 53 years. In Figure 1 the level of education both of group R and of group P is given.

Aspects of disease and side effects of irradiation

We asked the patients to describe their disease. It appeared that patients were well informed about this, good knowledge was judged in 84% of the cases. The vast majority (89%) of the patients knew exactly what therapy had to be given (group P). In group R this percentage was 88%. The aim of the treatment, curative intent or not, was correctly answered in both groups. The majority of patients could mention the most important (expected) side effects of the irradiation: fatigue, oesophagitis (in case of irradiation of the internal mammary chain), and local complaints like skin effects (erythema, epidermolysis), painful chest, itching and swelling of the breast (in case of breast conserving therapy) (Fig. 2).

Specific aspects of the trial

All patients were aware of the fact that they were candidates for participation in a phase-III clinical trial. Furthermore, patients answered a number of open questions. These questions concerned the total number of fractions, the duration of each treatment session and the total duration of the irradiation (in weeks). All these questions were answered correctly. It appeared that 21 of the 27 patients of group P stated that they were aware of the fact that the decision whether to irradiate the internal mammary chain (including the ipsilateral supra clavicular chain) or not was determined by chance. One-third of these patients said that they were not aware of the fact that they could withdraw their participation from the trial. Six patients mentioned that they were not aware of the fact that other treatment options were available.

Specific aspects of the informed consent procedure

The majority of patients had had one talk with their physician specifically dealing with the content of the trial. In group P, 2 patients had 2 talks and in group R, 1 patient had 2 talks. The mean duration of these talks were 33 minutes (range 5–90) in group P and 36 minutes (range 10–90) in group R, respectively. Patients in both groups stated that their physician spent sufficient time. They also stated that sufficient time was available to raise questions and that these questions were answered adequately. Respectively 93% in group P and 92% in group R were satisfied with respect to the informed consent procedure. In both groups, 1 patient stated that she was only moderately satisfied. In group P, 4 patients stated that they found it difficult to take a decision. In group R 6 patients stated that they found it very difficult to take such a decision. The time necessary to take a decision (after the first talk with the physician) varied considerably. The mean duration in group P was 3.5 days and in group R 4.8 days. Most patients stated that they found this

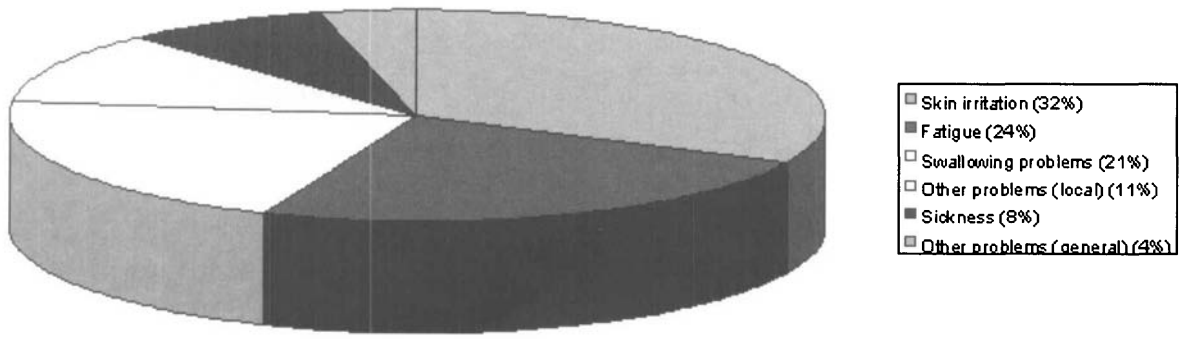

Figure 2. Most important (expected) side effect, as mentioned by patients (n=51)

https://doi.org/10.1017/S1460396900000261 Published online by Cambridge University Press

an important item. Patients were also asked if they had been given enough time to make a decision. In group P 7 patients stated that the time to make a decision was too short. Two of these patients, however, had agreed to participate immediately. The other 5 patients needed 3 days to decide whether to participate or not, but still found that this period was too short. For group R the same results were found (Fig. 3).

The aim was to give all patients written (general) information of the "Dutch Cancer Society" about scientific research on patients with cancer. Ultimately, 50% of the participants of the trial actually received this special kind of information and were specifically asked whether they appreciated it. All of them stated that they found this information very useful. A letter, specifically dealing with the content of the study, had to be given to all patients. For 6 patients who stated that they didn't receive this letter we checked if this was the case. In 5 cases we observed that the signed informed consent letters were present in the medical records. It appeared that these 5 patients had obviously signed for the fact that i) they agreed to participate in the trial; ii) they had received the letter about the content of the trial; iii) they were informed about the trial by their physician. The medical report of the sixth patient could not be found. One specific physician saw the majority of patients. This was the case for 17 patients in group P and 9 patients in group R. Eventually this may be a bias in this study. However, no differences with the other patients were seen.

Most important reasons to participate or refuse participation.

Most patients stated that they wanted to participate in this trial since they thought that their prognoses might hereby increase. Some patients said that they hoped that more knowledge about the efficacy of irradiation of the internal mammary chain (and the ipsilateral supraclavicular chain) might be of benefit for future patients. All patients who stated that they did not want to participate in the trial, said that they doubted the efficacy the irradiation of the

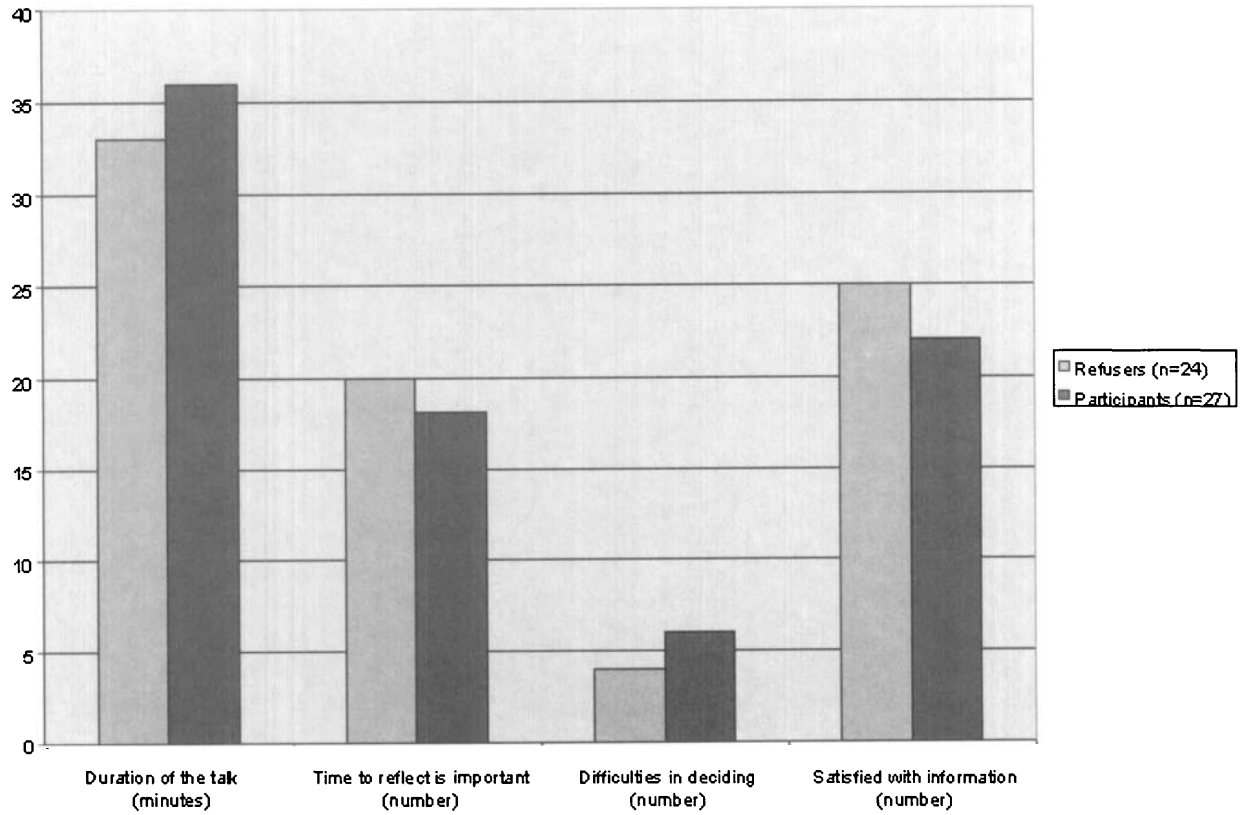

Figure 3. Specific aspects of the informed consent procedure.

https://doi.org/10.1017/S1460396900000261 Published online by Cambridge University Press

internal mammary chain (and the ipsilateral supra clavicular chain). Patients of group R also stated that the fear of risks and side effects played an important role in their decision.

CONCLUSIONS

Concerning the social demographic data it appeared that both groups are very homogeneous. No differences with respect to age and education level were noted.

All patients were well aware of the most important aspects of their disease and the aim of their treatment.

Specific aspects with respect to the trial

Based on the answers given by the patients it can be concluded that all patients were well aware of various aspects of the irradiation. All were aware of the fact that they participated (or not) in a phase-III clinical trial. However, it appeared that not all of them were aware of the randomisation procedure (or they could not remember this).

Informed consent

All patients stated that sufficient time was spent in the talks with the physician. No significant differences were noted between group P and group R with respect to the duration of the conversations, the duration of time necessary to make a decision and the degree of difficulty to make a decision. Fourteen patients however, stated that they found that they had to take a decision too quickly.

DISCUSSION

Various aspects of the informed consent procedure have been discussed in the literature and a number of recommendations have been suggested .[3–6] It has been stated that the treating physician should not ask for informed consent, since this might lead to a conflict of interest. It has been advocated also that this kind of information should preferably be given by more than one person. Finally, it was recommended that an adequate informed consent procedure should consist of at least three subsequent talks.

Furthermore, we note that some trials are easy to explain and some trials are difficult to explain to the patient. With respect to this item, the type of trial (phase I, II, III or IV), the type of treatment as well as the level of expected side effects are of great importance. From this research we conclude that an informed consent procedure should be adjusted to the type of trial. All recommendations, as mentioned above, need to be considered. Subsequently, a procedure should be determined. It is, of course, of importance to know how the law regulates the procedure. Finally, we conclude that the quality of the informed consent procedure should be evaluated. We think that, ideally, this type of analysis should always be performed at the start of a (large) trial. By doing so the quality of the informed consent procedure can be adapted to the results of the analysis. In our study we found that the quality of informed consent can be measured adequately. We recommend that 1 week should be given to patients to decide whether or not to participate in such a trial. However, if certain patients state that they do not need the extra week, they should not be forced to do so.

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