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Delphi consensus

# Which benefits and harms of preoperative radiotherapy should be addressed? A Delphi consensus study among rectal cancer patients and radiation oncologists

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ABSTRACT

*Background and purpose:* We previously found considerable variation in information provision on preoperative radiotherapy (PRT) in rectal cancer. Our aims were to reach consensus among patients and oncologists on which benefits/harms of PRT should be addressed during the consultation, and to assess congruence with daily clinical practice.

*Materials and methods:* A four-round Delphi-study was conducted with two expert panels: (1) 31 treated rectal cancer patients and (2) 35 radiation oncologists. Thirty-seven possible benefits/harms were shown. Participants indicated whether addressing the benefit/harm was (1) essential, (2) desired, (3) not necessary, or (4) to be avoided. Consensus was assumed when ⩾80% of the panel agreed. Results were compared to 81 audio-taped consultations.

*Results:* The panels reached consensus that six topics should be addressed in all patients (local control, survival, long term altered defecation pattern and faecal incontinence, perineal wound healing problems, advice to avoid pregnancy), three in male patients (erectile dysfunction, ejaculation disorder, infertility), and four in female patients (vaginal dryness, pain during intercourse, menopause, infertility). On average, less than half of these topics were addressed in daily clinical practice.

*Conclusions:* This study showed substantial overlap between benefits/harms that patients and oncologists consider important to address during the consultation, and at the same time poor congruence with daily clinical practice.



Preoperative radiotherapy (PRT) improves local control of rectal cancer. Although not demonstrated in randomised controlled trials, there might be a small survival benefit at the population level [1,2]. Due to the good local control with surgery alone, there is a high number needed to treat to prevent one local recurrence [2,3]. In addition, PRT is associated with adverse outcomes, such as higher chances of bowel and sexual dysfunction than with surgery alone [3,4]. When deciding about treatment, the possible benefit in terms of local control should therefore be balanced against the possible harms, taking into account patient preferences. Patients need to be informed about the most relevant benefits and harms of treatment in order to develop a preference. Informing patients also prevents them from overestimating the impact of treatment on cure [5]. Moreover, patients who are well-informed experience better health-related quality of life and may cope better with treatment side effects [6,7].

In earlier research, we found considerable variation in information provision regarding benefits and harms of PRT during the decision consultation between rectal cancer patients and their radiation oncologist [8]. This variation indicates a lack of clarity on which benefits and harms of PRT should be discussed with newly-diagnosed patients. In general, treatment guidelines provide little or no recommendation on which benefits and harms to communicate to patients. The Dutch guidelines for the treatment of rectal cancer for example state that clinicians need to 'discuss the possible benefits and harms of radiotherapy with the patient', without further specification [9].

The aims of this study were to (1) reach consensus among rectal cancer patients and radiation oncologists and compose a core list of benefits and harms of PRT that should minimally be addressed during the decision consultation, and (2) assess congruence with daily clinical practice.

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## Materials and methods

### Participants

A Delphi study was performed in two panels: treated rectal cancer patients and radiation oncologists. One of the most critical requirements in the Delphi method is the selection of experts, rich in information and experience [10]. Eligible patients had received radiotherapy and had finished their oncologic treatment at least 4 months ago. Patients treated at the Leiden University Medical Center who participated in an earlier study were approached via mail. Furthermore, members of the Dutch colorectal cancer patient organization were approached through the monthly newsletter of their association. Members of the Gastrointestinal-subsection of the Dutch Society for Radiation Oncology were approached for participation. All 45 radiation oncologists who were members of this platform were considered to be clinical experts.

We aimed to include at least half of the radiation oncologists from the platform, and an equal number of rectal cancer patients.

### Design

In order to reach consensus, we used the Delphi technique. This is a structured process that uses a series of questionnaires or 'rounds' to gather information until consensus in the panels is reached [11]. As we expected differences in opinions between patients and radiation oncologists, we aimed to reach consensus in each panel separately [12]. Based on previous Delphi studies, we intended a maximum of three online rounds in which participants could indicate which benefits and harms should always be addressed during the decision consultation [11]. Since there was only consensus on a limited number of benefits/harms after three rounds, we organized additional and separate consensus meetings with a fourth and final voting round. Between January and September 2013, the participants completed an iterative series of four questionnaires with feedback reports. In the first online questionnaire, socio-demographic and treatment- (patients) or work- (radiation oncologists) related details were obtained.

To assess congruence between the results of this Delphi-study and daily clinical practice, we compared the core list that was obtained to results of a previous study on information provision regarding benefits and harms of PRT [8]. In that study, we audiotaped and analysed 81 decision consultations between radiation oncologists and rectal cancer patients.

### Questionnaire rounds

The first questionnaire consisted of 37 benefits and harms, ordered by subject matter (see Table 1). These were obtained from all benefits/harms that had been discussed in any of the first 45 of 81 previously audio taped decision consultations between radiation oncologists and rectal cancer patients [8]. Benefits/harms related to inconvenience or costs were excluded. We complemented the list with outcomes described in the literature [2,3,13–18]. This led to a total of 30 outcomes on which PRT could have an effect for all patients, three for male patients only, and four for female patients only. In both panels, the same brief description of the items was given to help minimize interpretation differences. Information on probable prevalence was given in words and ranges (rare: 0–5%; sometimes: 5–25%; often: 25–75%; (almost) always: 75–100%).

Participants were asked to indicate whether they thought that addressing the outcome during the first consultation was (1) essential, (2) desired, (3) not necessary, or (4) to be avoided. Participants were asked to respond to all outcomes. For example, *all* participants (including female patients) were asked to indicate the importance of addressing 'erectile dysfunction' during consultations with male patients. After each subject matter, participants could comment on the item descriptions or suggest additional outcomes. The first questionnaire was pilot-tested in eight radiation oncologists and eight lay people. The final version of the first questionnaire was adjusted according to their feedback.

**Table 1**
Benefits and harms of preoperative radiotherapy presented in the first Delphi-round.

| |
|---|
| 1. Local control |
| 2. Overall survival |
| 3. Secondary tumours |
| 4. Altered defecation pattern (short term) |
| 5. Altered defecation pattern (long term) |
| 6. Faecal incontinence (short term) |
| 7. Faecal incontinence (long term) |
| 8. Soiling |
| 9. Increased rectal blood loss |
| 10. Decreased rectal blood loss |
| 11. Small bowel adhesions |
| 12. Bladder dysfunction |
| 13. Urinary incontinence |
| 14. Infertility (women) |
| 15. Infertility (men) |
| 16. Avoidance of pregnancy |
| 17. Erectile dysfunction (men) |
| 18. Ejaculation disorder (men) |
| 19. Vaginal dryness (women) |
| 20. Pain during intercourse (women) |
| 21. Menopause (women) |
| 22. Anastomotic leakage |
| 23. Increased blood loss during surgery |
| 24. Abdominal wound healing problems |
| 25. Perineal wound healing problems |
| 26. Increased readmission rate |
| 27. Nerve damage (short term) |
| 28. Nerve damage (long term) |
| 29. Muscle weakness |
| 30. Skin irritation |
| 31. Hair loss (local) |
| 32. Fatigue |
| 33. Longer recovery |
| 34. Feeling unwell |
| 35. Less appetite |
| 36. Cardiovascular problems |
| 37. Fistula |

Based on the literature, we defined consensus as at least 80% of the participants in one panel ticking the same answer category (e.g., 1 'essential') and no more than 15% an answer category two or three categories away (e.g., 3 'not necessary' or 4 'avoid') [11]. Outcomes on which consensus was reached were removed from the subsequent questionnaire(s). The other items were included in the subsequent questionnaire, together with feedback on the responses of the panel and the participant's own responses. Radiation oncologists also received feedback on patients' responses. Feedback on participants' responses in each of the categories was shown as a percentage and a column bar. In the second and third questionnaire, participants were asked to reconsider their previously given responses in light of the opinion of other panel members.

### Consensus meetings

After the three online questionnaires, we organized a separate in-person consensus meeting for each panel, with the aim to discuss the importance of addressing benefits/harms for which no consensus had been reached in the online rounds. All participants who had completed the third round were invited. The meetings