Chapter 5

Probabilities of benefit and harms of preoperative radiotherapy for rectal cancer: What do radiation oncologists tell and what to patients understand?

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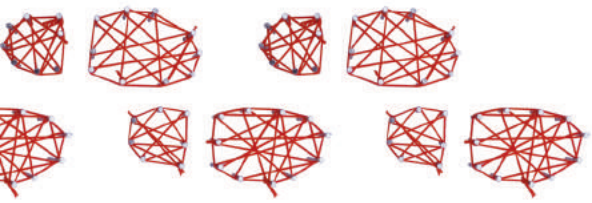

Abstract

Objective: Probabilities of benefits and harms of treatment may help patients when making a treatment decision. This study aimed to examine 1) whether and how radiation oncologists convey probabilities to rectal cancer patients, and 2) patients' estimates of probabilities of major outcomes of rectal cancer treatment.

Methods: First consultations of oncologists and patients eligible for preoperative radiotherapy (PRT) (N=90) were audiotaped. Tapes were transcribed verbatim and coded to identify probabilistic information presented. Patients (N=56) filled in a post-consultation questionnaire on their estimates of probabilities.

Results: Probabilities were mentioned in 99% (local recurrence), 75% (incontinence), 72% and 40% (sexual dysfunction in males and females, respectively) of cases. Most patients (89%) correctly estimated that PRT decreases the probability of local recurrence, and 10% and 38%/54% that it increases the probability of incontinence and sexual dysfunction in males/females, respectively. Patients tended to underestimate the probabilities of harms of treatment.

Conclusion: Our results show that oncologists almost always mention probabilities of benefit of PRT. In contrast, probabilities of harms often go unmentioned. The effect of PRT on adverse events is often underestimated.

Practice implications: Oncologists should stay alert to patients' possible misunderstanding of probabilistic information and should check patients' perceptions of probabilities.

Introduction

Determining the best choice when facing a treatment decision can be difficult for both clinicians and patients. Over the past decades, patients have become more actively involved as partners in the decision making process.[1] In particular for 'preference-sensitive' decisions, i.e., decisions for which there is insufficient evidence or in which individuals might value benefits and harms of treatment markedly differently, shared decision making (SDM) has become increasingly important.[2] One such preference-sensitive decision is the decision on neo-adjuvant short-course preoperative radiotherapy (PRT) in the treatment of localized rectal cancer.[3] The beneficial effect of PRT on local control in patients with localized rectal cancer has been clearly demonstrated.[4] However, PRT has not been shown to convey an additional survival advantage[4] and is associated with a higher risk of adverse effects, most importantly faecal incontinence and sexual dysfunction.[5-7] Difficulties arise in selecting those patients who benefit most from PRT, which makes it even more relevant to enable individual patients to weigh the benefits and harms of treatment for themselves.

In the process of SDM, the clinical consultation is an opportunity for patients to learn about their treatment options, including no adjuvant treatment, the benefits and harms of each option, and to be supported in making decisions.[8] Communicating probabilities that are relevant to the treatment decision is complex but essential, as probabilities often are the foundation of clinicians' treatment recommendation and help determine the importance of potential benefits and harms. Research has shown that the format (i.e., words, numbers) in which probabilistic information is presented can have significant effects on patients' interpretation of probability and their readiness to undergo treatments.[9-11] If probabilistic information is presented in words rather than in numbers, patients tend to have a less accurate interpretation of probabilities and overestimate the probability of an adverse event occurring.[11-14] Furthermore, presenting patients with relative risks appears more persuasive in making health care decisions than presenting the corresponding absolute risks.[9]

To date, research on effective methods for risk communication has primarily focused on written communication and the textual or visual representation of probabilities, including the application of these methods in decision aids.[15-17] To our knowledge, research on oral risk communication during clinical consultations in which treatment decisions are made has received no attention.

This study had a dual objective. The first aim of the study was to examine whether and how radiation oncologists provide probabilistic information, specifically in what proportion of risk statements they convey a probability using words, numbers, or both, and whether these proportions or the overall number of probabilities mentioned is associated with patients' age, gender and educational level. The second aim was to examine patients' estimates of probabilities of major outcomes of rectal cancer treatment (local control, faecal incontinence, sexual dysfunction), namely, if patients' estimates are correct and whether correct estimates is associated with the format used to communicate probabilities and with patients' age, gender and educational level.

Methods

Study population

The study was conducted at six of the 18 radiation centres in the Netherlands in the context of a large ongoing multicentre study on communication and treatment decision making during first consultations on PRT. All rectal cancer patients eligible for short-course PRT followed by a low anterior resection (sphincter-saving operation, with a possible risk of faecal incontinence), were eligible for inclusion. All radiation oncologists treating patients with rectal cancer were asked to participate.

Procedure

First consultations, in which the decision about PRT is usually made, of radiation oncologists with consecutive primary rectal cancer patients were audio taped. Participating patients signed an informed consent form and completed a questionnaire to assess socio-demographic details prior to the consultation. Patients were also asked to fill in a questionnaire within one week of the consultation, to assess their estimates of probabilities of major outcomes of rectal cancer treatment. Patients who filled in the post-consultation questionnaire more than 14 days after the consultation were excluded from the analyses (N=3). Radiation oncologists were asked to fill in a questionnaire assessing their socio-demographic and work-related details at the start of the study.

The Medical Ethics Committee of Leiden University Medical Centre approved the study.

Measures

Audio tapes of consultations were transcribed verbatim and coded using the ACEPP (Assessing Communication about Evidence and Patient Preferences) coding scheme.[18] By using this scheme, presented evidence relating to treatment outcomes was identified. Utterances conveying a probability of a patient experiencing benefit and/or harms of treatment were coded as a word ('verbal label'), a number, or both, as applicable. If a verbal label was used, we coded whether the label conveyed a direction of the *effect* of PRT ('yes', e.g., *smaller* chance; or 'no', e.g., *small* chance). If a number was used, we coded whether a percentage, a natural frequency (e.g., "5 out of 100"), or both were used. Also, we coded whether the number represented an absolute risk (e.g., "5 out of 100" or "35%"), an absolute risk reduction (e.g., "5% less chance" or "60% of patients with treatment, but 20% of patients fewer without treatment"), a relative risk (e.g., "twice as likely" or "will halve your risk"), or a range around risk (e.g., "about 30-40 patients"). If multiple formats were used to express numerical probabilities on one benefit/harm, all formats used were coded and therefore, categories of numbers mentioned do not add up to 100%.

Two independent raters coded the same ten (11%) audiotapes. Inter-rater reliability was high (Cohen's K = 0.80). The remaining tapes were each coded by one rater only; intra-rater reliability based on eight (9%) tapes per rater coded twice with a time difference of 19 months was substantial (Cohen's K = 0.67-0.92).

The major benefit of PRT described in the literature is local control, and major harms are faecal incontinence and sexual dysfunction. In the post-consultation questionnaire, patients were asked to indicate side-by-side the absolute probability ranges of each of these three outcomes occurring as a result of one of two treatment strategies: surgery only and PRT followed by surgery (multiple-choice questions, see Figure 1). The question on local control was framed in terms of 'local recurrence', as we expected this framing to be used in communicating probabilities in daily clinical practice. The question on sexual dysfunction was matched to the patient's gender. For each outcome, we considered patients' answers to be correct if they could reproduce the numerical probabilities that their oncologist had mentioned (i.e., risk recall). If no numerical probability was mentioned, we considered patients' answers to be correct if they ticked the probability ranges for the group averages, as reported in key publications and in the Dutch treatment guidelines (i.e., risk interpretation).[3;7;19;20] From this point forward, recall and interpretation will be referred to as 'estimate'. If patients' responses indicated that with PRT followed by surgery, compared to surgery only, the probability of a local recurrence is lower, or that the probability of faecal incontinence or sexual dysfunction is higher, we considered the response to reflect the correct effect of PRT.

Of 100 people who have been treated for a tumour in the rectum, **in how many will the disease recur within 5 years** after treatment with …

a)… radiotherapy followed by surgery?	b)… surgery only?
☐ no one	☐ no one
☐ 1 to 5	☐ 1 to 5
✔ 6 to 10	☐ 6 to 10
☐ 11 to 15	✔ 11 to 15
☐ 16 to 20	☐ 16 to 20
☐ more than 20	☐ more than 20

Of 100 people who have been treated for a tumour in the rectum, **how many will experience leakage of stools in the years** after treatment with …

a)… radiotherapy followed by surgery?	b)… surgery only?
☐ no one	☐ no one
☐ less than 30	☐ less than 30
☐ 30 to 50	✔ 30 to 50
✔ 51 to 70	☐ 51 to 70
☐ more than 70	☐ more than 70

Only for MEN:

Of 100 men who have been treated for a tumour in the rectum, **how many will be confronted with sexual problems** (erection problems and/or ejaculation problems) in the years after treatment with …

a)… radiotherapy followed by surgery?	b)… surgery only?
☐ no one	☐ no one
☐ less than 40	☐ less than 40
☐ 40 to 60	✔ 40 to 60
✔ 61 to 80	☐ 61 to 80
☐ more than 80	☐ more than 80

Only for WOMEN:

Of 100 women who have been treated for a tumour in the rectum, **how many will be confronted with sexual problems** (vaginal dryness and/or pain during intercourse) in the years after treatment with …

a)… radiotherapy followed by surgery?	b)… surgery only?
☐ no one	☐ no one
☐ less than 10	☐ less than 10
☐ 10 to 20	✔ 10 to 20
✔ 21 to 30	☐ 21 to 30
☐ 31 to 40	☐ 31 to 40
☐ more than 40	☐ more than 40

Figure 1. Multiple-choice questions on the interpretation of risks of major outcomes of PRT. Correct answer boxes per outcome and treatment strategy are ticked and were based on key publications and on the Dutch treatment guidelines.

Statistical analyses

Descriptive statistics were used to report patients' and radiation oncologists' characteristics, and information provision on the probability of patients experiencing benefits and/or harms of treatment. The overall number of probabilities mentioned and the number of verbal labels, numbers, or both used per consultation were not normally distributed, so medians are presented and were compared by patients' gender and patients' interpretation with Mann-Whitney U-tests. Spearman correlations were used to measure linear dependence between overall number of probabilities addressed and number of verbal labels, numbers or both used, and patients' age. Logistic regression analysis was conducted to assess the association between the discussion of probabilities (yes/no) and patients' age. Using χ^2 tests, patients' correct estimate of probabilities (yes/no) and patients' correct estimate of the effect of PRT (yes/no) were compared by oncologists' use of verbal labels only and by patients' gender and education. Significance testing was done two-sided at $\alpha = 0.05$.

Results

Participants

We approached 128 eligible patients, all diagnosed between November 2010 and April 2014. Twelve patients (9%) could not be reached and twenty-one (17%) refused to participate. Ninety-five patients (74%) agreed to have their consultation audio taped. Five of them were excluded from the analyses because their consultation had not been audio taped completely. Of the remaining 90 patients, 56 (62%) completed the post-consultation questionnaire, a median of five days after the consultation (range, 0-13). Patients were on average 64 years old (range, 40-87), and the majority (73%) were male (Table 1). No significant differences were found for patients' age, gender or educational level between those who did versus did not complete the post-consultation questionnaire. All 21 radiation oncologists approached for the study agreed to participate and audiotaped a median of four consultations (range, 1-11).

Table 1. Participants' characteristics

	N
Patients (N=90)	
Mean age, years ± s.d. (range)	64 ± 10.1 (40-87)
Male	66 (73%)
Educational level[a]	
Low	17 (33%)
Intermediate	32 (44%)
High	26 (22%)
Radiation oncologists (N=21)	
Mean age, years ± s.d. (range)	40 ± 6.5 (27-52)
Male	6 (29%)[b]
Median time since specialization, years (range)	6 (0-20)
Median number of rectal cancer patients per month (range)	3 (1-8)

[a] Educational levels included low = completed no/primary school; intermediate = completed lower general secondary education/vocational training; or high = completed pre-university education/high vocational training/university. Eighteen patients did not respond to this question.

[b] Male radiation oncologists audio taped a total of 19 consultations (21%).

Oncologists' overall provision of probabilistic information on benefits/harms

In the 90 consultations, 611 benefits and harms of PRT were mentioned (Md=7 per consultation; range, 2-12) (Table 2). The oncologists mentioned the probability of their occurrence for 358 benefits and harms (59%, Md=4 per consultation; range, 0-8). The oncologists mentioned significantly fewer probabilities in consultations with less compared to more educated patients (Md 'Low education'=3, 'Intermediate education'=4, 'High education'=5 probabilities per consultation, $F(2,69)=7.52$, $p=0.001$). There was no significant association between the number of probabilities the oncologists mentioned and patients' age or gender.

Table 2. Communication of probabilities of treatment outcomes of PRT followed by surgery and frequency of formats used in N=90 consultations

Frequency	LR N (%)	F. Inc N (%)	Sex M N (%)	Sex F N (%)	Total major outcomes N (%)	All outcomes (incl major) N (%)
All consultations	**N=90**	**N=90**	**N=66**	**N=24**	**N=90**	**N=90**
Outcome addressed in consultation	89 (99)	51 (57)	61 (91)	15 (63)	216	611
When outcome is addressed	**N=89**	**N=51**	**N=61**	**N=15**	**N=216**	**N=611**
Probability mentioned	88 (99)	38 (75)	44 (72)	6 (40)	176 (81)	358 (59)
When a probability is mentioned	**N=88**	**N=38**	**N=44**	**N=6**	**N=176**	**N=358**
Verbal label only	12 (14)	19 (37)	24 (39)	3 (50)	58 (33)	220 (61)
Number only	24 (27)	9 (18)	11 (18)	2 (33)	46 (26)	57 (16)
Verbal label and number	52 (58)	10 (20)	9 (15)	1 (17)	72 (41)	81 (23)
When a verbal label is mentioned	**N=64**	**N=29**	**N=33**	**N=4**	**N=131**	
Direction of PRT-effect mentioned	57 (89)	20 (69)	20 (61)	3 (75)	100 (77)	
When a number is mentioned*	**N=76**	**N=19**	**N=20**	**N=3**	**N=118**	
Percentage	52 (68)	18 (94)	17 (81)	2 (67)	89 (75)	
Natural Frequency	12 (16)	1 (5)	0	0	13 (11)	
Absolute risk	18 (24)	11 (58)	11 (55)	1 (33)	41 (35)	
Absolute risk reduction	49 (64)	13 (68)	9 (45)	1 (33)	72 (61)	
Relative risk	52 (68)	2 (26)	2 (10)	0	54 (46)	
Range around	16 (21)	7 (37)	2 (10)	1 (33)	26 (22)	

Abbreviations: PRT = Preoperative radiotherapy; LR = Local recurrence; F. Inc = Faecal Incontinence; Sex M = Sexual dysfunction males; Sex F = Sexual dysfunction females. * Categories of numbers mentioned do not add up to 100%, because multiple categories can apply to a probability statement.

Patients' estimates of probabilities

The patients selected the correct absolute probability ranges of both surgery only and PRT followed by surgery, in 12/56 cases (21%) for local recurrence, 0/52 cases (0%) for faecal incontinence, 3/39 cases (8%) for sexual dysfunction in males, and 4/14 cases (29%) for sexual dysfunction in females.

Patients had a slight tendency to *overestimate* the probability of a local recurrence for treatment with surgery only (Figure 2a). For PRT followed by surgery, patients' estimates of a local recurrence were spread across categories. All patients *underestimated* the probability of faecal incontinence for PRT followed by surgery, and the majority (61%) of patients also *underestimated* the probability for surgery only (Figure 2b). For both treatment strategies, male patients tended to *underestimate* the probability of sexual dysfunction (Figure 2c). Female patients' estimates of the probability of sexual dysfunction were spread across categories, with a slight tendency to *overestimate* the probability for surgery only and to *underestimate* the probability for PRT followed by surgery (Figure 2d).

Table 3 shows the percentage of patients who correctly interpreted the *effect* of PRT, compared to surgery only, on the major treatment outcomes. Most patients (89%) correctly interpreted that PRT decreases the probability of a local recurrence. Regarding faecal incontinence and sexual dysfunction in males and females, the patients correctly interpreted that PRT increases the probability in 10%, 38% and 54%, respectively. Of note, over one-third (38%) of patients believed that PRT decreases the probability of faecal incontinence. There were four patients (7%) who correctly interpreted the effect of PRT on all three major outcomes.

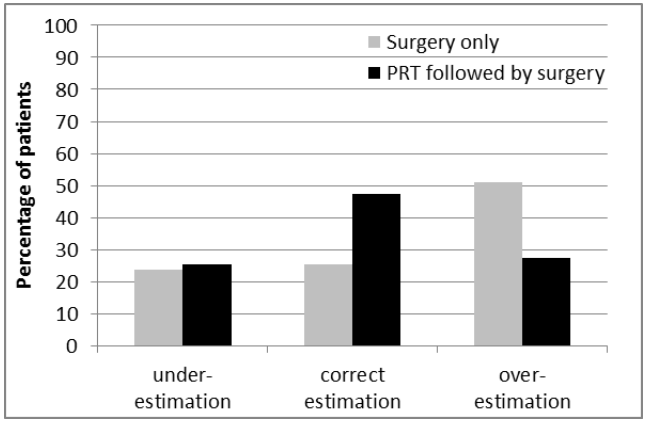

Figure 2a. Patients' estimates of probabilities of local recurrence
Abbreviation: PRT = Preoperative radiotherapy.

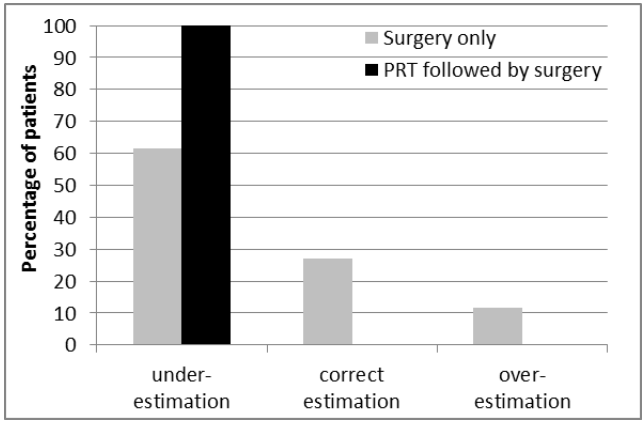

Figure 2b. Patients' estimates of probabilities of faecal incontinence
Abbreviation: PRT = Preoperative radiotherapy.

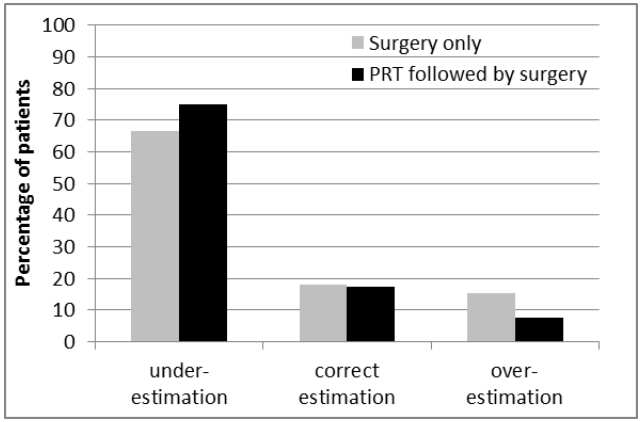

Figure 2c. Patients' estimates of probabilities of sexual dysfunction (males)
Abbreviation: PRT = Preoperative radiotherapy.

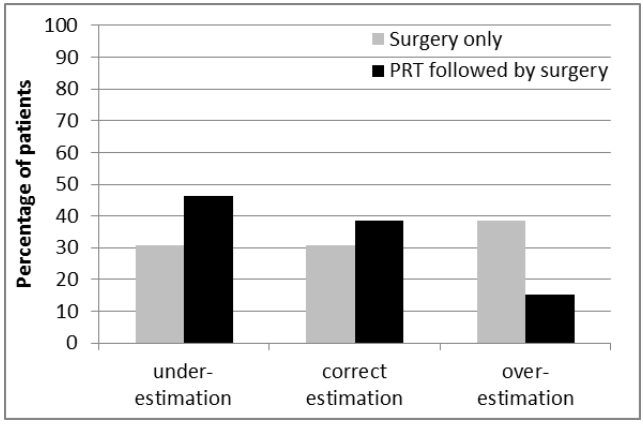

Figure 2d. Patients' estimates of probabilities of sexual dysfunction (females)
Abbreviation: PRT = Preoperative radiotherapy.

Table 3. Patients' interpretation of the effect of PRT followed by surgery on major treatment outcomes compared to surgery only

	Local recurrence N=56	Faecal incontinence N=52[a]	Sexual dysfunction males N=39[b]	Sexual dysfunction females N=13[b]
PRT decreases probability	89%	38%	13%	15%
PRT does not influence probability	9%	52%	49%	31%
PRT increases probability	2%	10%	38%	54%

Abbreviation: PRT = Preoperative radiotherapy. Grey boxes represent the correct effect of PRT followed by surgery, compared to surgery alone. [a] Four patients did not respond to this question. [b] Two patients did not respond to this question.

There was no significant association between the oncologists' use of either verbal labels only or numbers (with or without verbal labels) or the number of probabilities the oncologists mentioned during the consultation and whether patients correctly estimated the absolute probabilities or the direction of the PRT-effect on the treatment outcomes. Also, there was no significant association between whether the oncologists conveyed a direction of the effect of PRT (either by verbal labels or numbers) and patients' correct estimate of the effect of PRT. Further, there was no significant association between patients' age, gender or educational level and whether patients correctly estimated the absolute probabilities or the direction of the PRT-effect on the treatment outcomes.

Discussion and conclusion

Discussion

The first aim of this study was to describe the oncologists' provision of probabilistic information, and specifically in what proportion of cases when the oncologists mention a benefit/harm of treatment, they also convey a probability. Almost two-third of the times that a benefit or harm was discussed, the

oncologists also mentioned the probability of its occurrence, albeit significantly less frequently to patients with lower education. The major benefit of PRT described in the literature is local control, and major harms are faecal incontinence and sexual dysfunction. Earlier, we showed that oncologists as well as patients consider these topics important to address during the first consultation.[21] The current study showed that the (decreased) probability of local recurrence, the benefit of PRT, is virtually always mentioned during the consultation. In contrast, probabilities of major harms of PRT often go unmentioned. An explanation of the discrepancy may lie in two factors. The first may be that oncologists simply do not know the probabilities of the major harms as well as they know the probability of local recurrence. Another explanation may lie in the fact that oncologists think that PRT is the best option for the patient, and they either implicitly or explicitly use the persuasive strategy of selectively presenting the benefits of treatment.[22] Further, it is noteworthy that oncologists do not only discuss sexual dysfunction significantly more often with male than with female patients, as has been shown in previous research,[23] but they also mention its probability substantially more often to male patients. Not mentioning the probabilities of possible harms has been shown to be associated with less understanding of these harms and an increased acceptance of interventions that might do harm.[24]

When presenting probabilities of local recurrence, oncologists tended to present a relative risk, stating that PRT will cut by half its probability of occurrence. In a majority of these cases, the oncologists also gave information on the baseline absolute risk or the absolute risk reduction. Adding this information should be helpful to patients' understanding. Indeed, it has been shown that when relative risks are not accompanied by an absolute risk, they can steer patients towards accepting a treatment or intervention, since particularly with low baseline risks a relative risk reduction seems larger than an absolute risk reduction and the effect of treatment thus seems larger.[17]

The second aim of this study was to examine patients' estimates of probabilistic information on major treatment outcomes, and specifically if patients' estimates were correct. This was true for few patients. We were unable to find significant associations between formats used to convey probabilities and the correctness of patient's estimates, which might have been due to the limited number of patients returning the questionnaire.

In the majority the cases in which a probability of a major outcome was mentioned, the oncologists used a number, with or without the accompaniment of a verbal label. In one-third of the cases, only verbal labels were used. The latter should be discouraged as previous research has shown that the accuracy of patients' interpretation and patients' satisfaction are lower when only verbal labels are used, compared to when numbers are mentioned.[11;12] We found that patients tend to overestimate the probability of getting a local recurrence if adjuvant treatment with radiotherapy is foregone (e.g., treatment with surgery alone). Also, we found that patients tend to underestimate the probability of harms occurring after radiotherapy treatment. The findings of an overestimation of the small probability of local recurrence and an underestimation of the large probabilities of incontinence and sexual dysfunction are in line with prospect theory.[25] Since our crude way of assessing over- and underestimation is unlike the general way of assessment in prospect theory research, however, we are not sure whether it truly reflects the concept of probability distortion specified by this theory. This deserves further research.

We did not find an effect of the use of verbal labels only on patients' estimates of probabilities, possibly due to the small sample size of patients. In a systematic review on risk communication, Zipkin and colleagues recommended to improve patients' understanding by avoiding the use of verbal labels only, a recommendation which is widely supported.[15-17;26] Also, literature suggests that the use of illustrations or icon arrays might aid patients' understanding.[26]

Most, though not all, patients interpreted the effect of PRT on local recurrence correctly. In contrast, the effect of PRT on faecal incontinence and sexual dysfunction was most often estimated incorrectly. For example, over one-third of patients believed that PRT followed by surgery, compared to surgery only, decreases the probability of faecal incontinence, while in fact, PRT increases the risk from about 40 to 60%.[27] This suggests that many patients believe that there is no harm in undergoing PRT. There may be several explanations for patients' misinterpretations. Firstly, patients might not consider these harms important given the potential gain, and especially at this point in time when they are primarily focused on becoming disease-free. In earlier research, however, we found that rectal cancer patients consider both faecal incontinence and sexual dysfunction important topics to be discussed with the radiation oncologist at the time of decision making, and that they take these

harms in consideration when forming a treatment preference.[21;28] Secondly, patients might ignore these probabilities, as they believe that the treatment decision has already been made. In most of these first consultations, oncologists do not tell the patient that a treatment decision needs to be made.[29] This might lead to post hoc justification, that is, to patients having the desire to justify the prior decision as being the correct one, and one which will do them no harm.[30]

A strength of our study is that by audio taping the consultations, we were able to observe the actual communication between radiation oncologists and rectal cancer patients and therefore, we did not depend on oncologists' or patients' recall on which probabilities were mentioned. Our study also has potential limitations. The first is that because of relatively small numbers of patients included per oncologist, we were unable to assess associations between probabilities mentioned and oncologists' characteristics. Further, the range in the number of recorded consultations per oncologist might have led to somewhat skewed results. The second limitation is that only 57 of the 90 patients included in the study filled in the post-consultation questionnaire (within 14 days). Most (22/33, 67%) of the patients who did not complete the questionnaire only gave consent for audiotaping their consultation. Other patients returned the questionnaire without filling in the questions on risk interpretation, possibly because they did not know the answers or were uncomfortable with the questions. If this is the case, then the rates of correct estimates of probability ranges that we established, most probably are overestimations of actual understanding. Finally, patients might have received or searched for additional (probabilistic) information prior to the consultation or after the consultation and before completing the questionnaire. Again, this would imply that our results overestimate the number of patients who correctly estimate the probabilities of treatment outcomes based on the information given during the consultation.

Conclusion

Our results show that the probability of the additional benefit of PRT on local control is virtually always mentioned during the first and pre-treatment consultation. In contrast, probabilities of adverse events are often left unspoken. Most patients interpret the beneficial effect of PRT on local control correctly, but the effect of PRT on adverse events is most often underestimated.

Practice implications

In order for patients to understand and weigh the pros and cons of treatment, and in order for them to be involved in deciding about treatment, they need to be aware of the relevant probabilities of major outcomes. This is a challenge for oncologists who should be careful to mention both the probabilities of benefit and harms whenever possible and stay alert to patients' potential misunderstanding. It is recommended that oncologists regularly check patients' perceptions of probabilities during the consultation.

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