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Received: 27 May 2022 | Revised: 13 September 2022 | Accepted: 4 October 2022

DOI: 10.1002/ijc.34327

CANCER THERAPY AND PREVENTION

IJC INTERNATIONAL JOURNAL of CANCER

Patient preferences for active surveillance vs standard surgery after neoadjuvant chemoradiotherapy in oesophageal cancer treatment: The NOSANO-study

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Abstract

Active surveillance may be a safe and effective treatment in oesophageal cancer patients with a clinically complete response after neoadjuvant chemoradiotherapy (nCRT). In the NOSANO-study we gained insight in patients' motive to opt for either an experimental treatment called active surveillance or for standard immediate surgery. Both qualitative and quantitative analyses methods were used. Forty patients were interviewed about their treatment preference, 3 months after completion of nCRT (T1). Data were recorded, transcribed verbatim and analysed according to the principles of grounded theory. In addition, at T1 and T2 (12 months after completion of nCRT) questionnaires on health-related quality of life, coping, anxiety and decisional regret (only T2) were administered. Interview data analyses resulted in a conceptual model with 'dealing with threat of cancer' as the central theme. Patients preferring active surveillance tend to cope with this threat by confiding in their bodies and good outcomes. Their mind-set is one of 'enjoy life now'. Patients preferring surgery tend to cope by minimizing uncertainty and eliminating the source of cancer. Their mind-set is one of 'don't give up, act now'. Furthermore, questionnaire results showed that patients with a preference for standard surgery had a lower quality of life. Patient preferences are individualized and thus difficult to predict. Our model can help healthcare professionals to determine patient preferences for treatment. Coping style and mind-set seem to be determining factors here.

KEYWORDS
active surveillance, oesophageal cancer, patient preferences, treatment decision-making

Abbreviations: CRE, clinical response evaluation; CWS, Cancer Worry Scale; DRS, Decision Regret Scale; nCRT, neoadjuvant chemoradiotherapy; SANO, Surgery As Needed for Oesophageal cancer; STAI, State Trait Anxiety Inventory Scale; TMSI, Threatening Medical Situation Inventory.

Funding information
Maag Lever Darm Stichting, Grant/Award Number: ZP-18-13

What's new?

Active surveillance has become an alternative to standard surgery for oesophageal cancer patients with a clinically complete response after neoadjuvant chemoradiotherapy. This is the first study to explore the personal motivations for patients to opt for active surveillance or standard surgery. The results show that patients with a strong preference for active surveillance tend to cope with the threat of cancer by having faith in their bodies and good outcomes; patients with a strong preference for standard surgery tend to cope by minimizing the uncertainty. The model could support doctors and patients in reaching a well-informed and personalized treatment decision.

1 | INTRODUCTION

Neoadjuvant chemoradiotherapy (nCRT) followed by oesophagectomy is standard care for patients with oesophageal cancer.[1,2] However, in almost one third of these patients no viable tumour cells are found in the resection specimen after surgery.[2] This observation raised the question whether it is beneficial for all patients to undergo standard oesophagectomy after nCRT, given its association with 30-day mortality rates of 2.5%, high postoperative morbidity (60% of patients have at least one complication) and lasting negative effects on quality of life.[2,3]

An alternative to standard surgery after nCRT is active surveillance. Active surveillance consists of frequent clinical response evaluations (CREs) using endoscopy and imaging to assess tumour response after nCRT. Using this strategy, only when locoregional regrowth is histologically proven or highly suspected without any signs of distant metastases, oesophagectomy will be offered. A recent meta-analysis of retrospective studies showed that patients undergoing active surveillance have overall survival rates comparable to patients receiving immediate surgery after nCRT.[4] The safety and effectiveness of active surveillance is currently being investigated in the Dutch multicenter SANO-trial (*S*urgery *A*s *N*eeded for *O*esophageal cancer) and the French Esostrate-trial.[3,5] Data from these randomized trials are needed to definitively clarify the value and noninferiority of an active surveillance strategy.

Until now, it is unclear how patients weigh the possible advantages and disadvantages of active surveillance. A recent discrete choice experiment showed that patients are willing to give up 16% of 5-year survival to reduce the probability that oesophagectomy is necessary from 100% to 35%.[6] Contrarily, it has been suggested that the stress of frequent CREs may not outweigh the likelihood that surgery can be omitted.[7] So, patients treatment decisions are likely to be influenced by how they cope with uncertainty, stress and anxiety.[7,8] Coping styles typically studied in oncology are monitoring and blunting, respectively, the tendency to seek threat-relevant information and the tendency to cognitively avoid threat relevant information and seek distraction from threat.[9,10]

Making well-informed, thought-out and individually meaningful treatment decisions is challenging for both patients and their physicians.[11,12] This is especially true when the noninferiority of an experimental treatment has not been demonstrated yet, as is the case in active surveillance vs standard surgery after nCRT in oesophageal cancer treatment.[13] In the near future, the Esostrate- and SANO-trials will show whether active surveillance is noninferior to standard surgery. In the case of noninferiority, patient preferences will prevail in determining the treatment. Moreover, even when noninferiority is not established, it remains valid that patients have preference for the 'inferior' therapy. The current randomized trials offer the unique opportunity to investigate such strong preferences, as some patients refuse participation, and thus express strong preferences for one of the two treatment options. Understanding of what matters to oesophageal cancer patients in their decision-making process will help healthcare providers to attune to the patients' needs, and may contribute to shared decision-making.

2 | METHODS

2.1 | Study design, participants and procedures

The NOSANO-study is a psychological companion study of the SANO-trial, and focuses on patients' need for information and preferences for different treatment options. In this article, we report on patient preferences to opt for either active surveillance or standard surgery after nCRT, using a mixed methods design. Patients were interviewed in-depth about their treatment preference. In addition, psychological questionnaires related to topics that are expected to affect treatment preference were administered. These include questionnaires about health-related quality of life, anxiety and coping.

All patients who declined participation in the randomized SANO-trial because of a strong treatment preference for the other treatment, were consecutively invited to participate. Because our study accompanies the SANO-trial, the same inclusion criteria apply: operable patients with locally advanced resectable squamous cell carcinoma or adenocarcinoma of the oesophagus or oesophagogastric junction who are planned to undergo nCRT according to CROSS followed by surgical resection.[3] This means that all patients in this current study were recruited before nCRT. Patient recruitment was done until data saturation for the qualitative study part was reached.[14,15]

Patients were recruited from seven participating hospitals in the Netherlands. There were two moments of measurement. Interviews were administered at T1: after completion of nCRT, before knowledge

of clinically complete response and prior to surgery if applicable. Questionnaires were administered at T1 and additionally at T2: 12 months after nCRT, that is, after surgery if applicable.

2.2 | Measures

2.2.1 | Interviews

A topic list was designed for administering the interviews. At first the personal motives for patients' decision to opt for either active surveillance or standard surgery were broadly explored. Next specific topics were addressed: earlier experiences with illness and healthcare, future health expectations, emotional motives, religious or spiritual believes and values in life. Interviews were conducted by senior psychologist LK and trained psychologists GC and RC.

2.2.2 | Questionnaires

Quality of life was measured using the EQ-5D-5L, which provides a societal perspective and the EQ-VAS which provides a patient perspective on quality of life.[16] Trait anxiety was measured with the State Trait Anxiety Inventory Scale (STAI).[17] To measure concerns about developing cancer (again) and the impact of these concerns on daily functioning, the Cancer Worry Scale (CWS) was used.[18] Coping style was assessed using the Threatening Medical Situation Inventory (TMSI).[19] Finally, regret of the treatment decision was measured by the Decision Regret Scale (DRS), administered at T2 only.[20]

2.2.3 | Data analyses

The interviews took place at the treating hospital or at the patients' home, and were audio-recorded and transcribed verbatim. The interview data were analysed according to the principles of grounded theory,[15,21] using Nvivo software (version 20.3.1). To ensure the reliability and robustness of data-analyses, triangulation was applied: all interview data were read and analysed by three researchers (MH, RC, LK). Open and axial coding was done by RC, with weekly meetings with LK to discuss initial findings followed by comprehensive review and adjustment. In addition, two meetings with the research team (LK, SL, JB, JvL, BvdW) took place in this phase. These team meetings had the purpose to review and adjust initial findings. Furthermore, the meetings ensured that the data were considered from both a psychological and a medical perspective, given the divers professional background of team members. Selective coding was done by MH and LK. They independently worked towards an integrated theory, by using mind maps and coding matrices. They met weekly to discuss and compare their final theory. In between, one team meeting took place to discuss preliminary theory with the whole research team (SL, JB, JvL, BvdW, RC).

With regard to the analysis of the questionnaires, independent-samples *t* tests, and paired-samples *t*-tests (α set at 0.05) were used to make comparisons between the treatment groups and between the different time measurements T1 and T2. The questionnaires were analysed using IBM SPSS Statistics, version 25.

3 | RESULTS

3.1 | Patients

Forty-seven patients were invited for participation and 40 patients were enrolled in the study. Twenty patients preferred active surveillance and 20 patients preferred standard surgery. Figure 1 shows a flow chart of participant dropouts and reasons. Baseline characteristics of the 40 patients included are shown in Table 1.

3.2 | Interviews

The conceptual model is presented in Figure 2. The middle of the model shows the common ground of all patients: the threat of cancer. All patients react on this threat by striving for safety, but the way they do so differs. Patients opting for 'active surveillance' use a coping style that can be described as 'confidence'. Patient opting for surgery use a coping style of 'minimizing uncertainty'. In the text below, we discuss our model in more detail.

3.3 | Patients preferring active surveillance

3.3.1 | Coping style: Confidence

Patients who opted for active surveillance after nCRT felt like they were 'clean' and recovered after nCRT. They preferred to leave the period of cancer behind and get on with their lives ('*it is simple: I am cancer free, so I am not undergoing this surgery*'). The knowledge of them feeling good in that moment, and the knowledge that surgery could negatively change their lives' quality—in their opinion—made them confident in their decision to opt for active surveillance. They felt like it was a 'responsible risk' to refrain from surgery. However, they are not necessarily against surgery. Rather, they regarded surgery as something that is not necessary at the present moment ('*I feel very good right now, and I want to enjoy my life now and seize the day*'). Surgery is often referred to as the 'final back-up option' and considered as something they could undergo any time in the future anyway.

3.3.2 | Mind-set: 'Enjoy life now. Seize the day'

The choice for active surveillance seemed for most patients to derive from a mind-set of wanting to 'live in the present moment'. They do not want to worry about what might happen in the future, instead

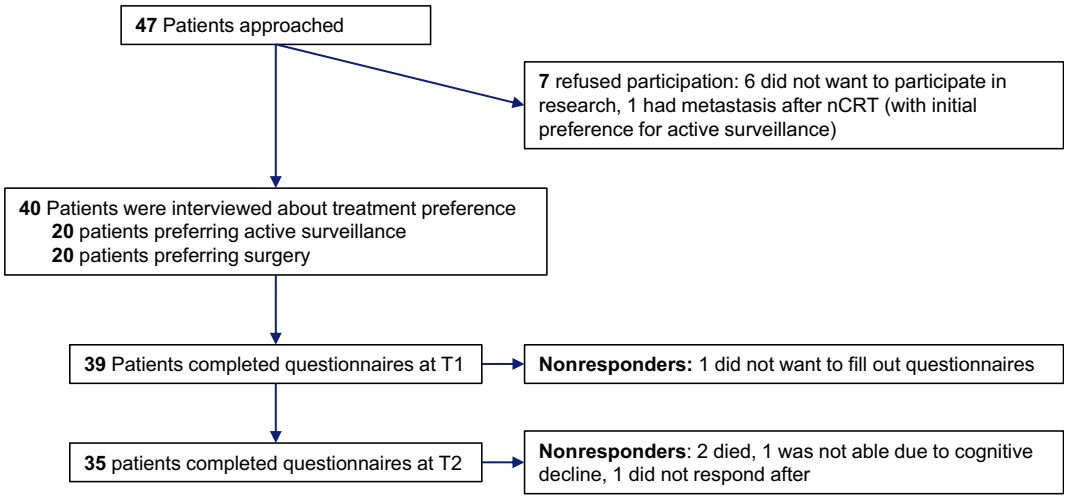

FIGURE 1 Flowchart of patient dropout and reasons

TABLE 1 Baseline characteristics of participants (N = 40)

	Active surveillance group (N = 20)	Standard surgery group (N = 20)
Sex (male)	12 (60%)	15 (75%)
Median age in years (range)	70.5 (55-78)	61 (51-79)
Tumour type/histology (%)		
Squamous cell carcinoma	6 (30%)	1 (5%)
Adenocarcinoma	14 (70%)	19 (95%)
Adenosquamous cell carcinoma	0 (0%)	0 (0%)
Clinical tumour stage		
cT1	0 (0%)	0 (0%)
cT2	7 (35%)	1 (5%)
cT2-3	1 (5%)	2 (10%)
cT3	11 (55%)	15 (75%)
cT4	1 (5%)	1 (5%)
Missing	0 (0%)	1 (5%)
Clinical lymph node stage		
N0	7 (35%)	8 (40%)
N0-1		1 (5%)
N1	8 (40%)	5 (25%)
N2	5 (25%)	4 (20%)
N3	0 (0%)	1 (5%)
Missing	0 (0%)	1 (5%)
Clinical M stage		
M0	20 (100%)	20 (100%)

they trust in good outcomes. They tended to describe the recurring tests and results of active surveillance as something 'they just have to deal with' and something they should not worry about ('*It is part of the deal, there is no point in worrying; I should not go round in sackcloth and ashes*').

3.3.3 | Quality of life

One of the reasons patients opted for active surveillance was their wish to maintain their quality of life. They were aware of the possible impact of surgery on their day-to-day life and that quality of life will likely never return to its old level. By choosing to postpone and hopefully avoid surgery, they have the feeling of control over the situation; at least they can 'choose' to maintain their quality of life. As one patient stated: ('*It is major surgery, which comes with consequences about how life will be afterwards. That is my biggest fear; my quality of life has always been so good [..] that can't become better after surgery, it will only become worse. And that made me think: I'm not going to have this surgery*'). Furthermore, patients expected surgery to make them dependent on others and make them feel like 'being a patient'. By opting for active surveillance they try to avoid that.

3.3.4 | Reasons against choosing for standard surgery

Next to reasons to opt for active surveillance as mentioned above, patients mentioned specific reason to opt out of surgery. The fact that surgery does not 100% guarantee a cure plays a role in the considerations patients made for choosing active surveillance. Also, the surgical procedure itself weighed against choosing for surgery. For example, some patients reported a fear of not waking up from anaesthesia, or they were afraid of complications.

3.4 | Patients preferring standard surgery

3.4.1 | Coping style: Minimize uncertainty

Patients preferring surgery, reported to appreciate the safety and security that the cancer will be removed. Interestingly, some indicated that they still 'feel' that the cancer exists in their body, even

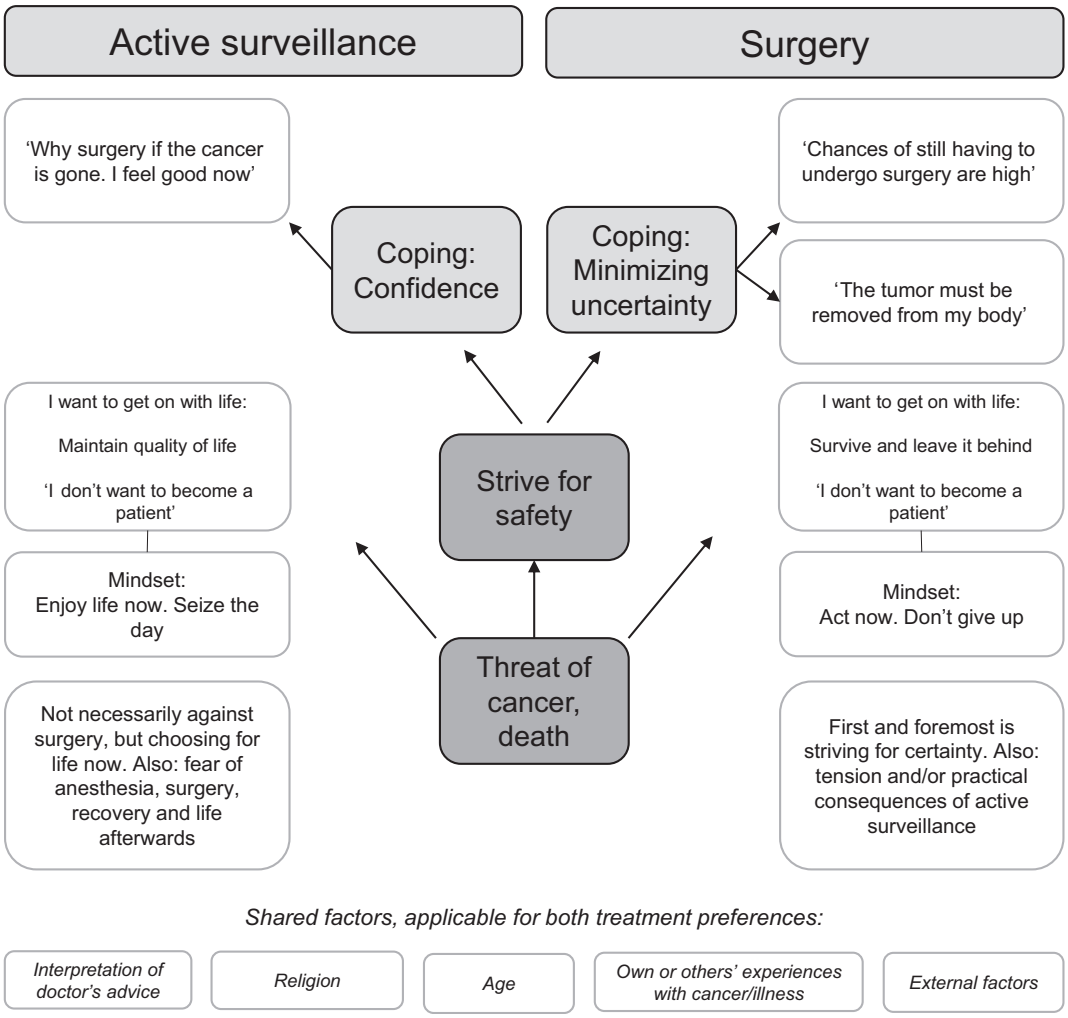

FIGURE 2 Conceptual model of the main results. Central is the strive for safety in a situation where patients are threatened by cancer and death. Patients differ in how they cope with this threat

though diagnostic tests have shown otherwise ('*Well, if you ask me, the tumour is not gone yet, because I can still feel it. [..] you don't know this for sure, of course, but yes, most importantly, the insecure feeling is mentally challenging and I don't like that*'). Some patients stated that they did not trust their bodies anymore and thus wanted every sick part of their body to be removed ('*My body has failed me, and who says this isn't going to happen again*'). Patients were eager to have the cancer treated before it gets the chance of progressing. They do not feel comfortable with 'wait and see' how the disease might develop.

3.4.2 | Mind-set: 'Act now. Don't give up'

The fear of dying and the desire to fight against this fear, was the reason for this group to prefer surgery over active surveillance. By choosing for surgery, patients felt like they were fighting and taking action ('*If the cancer re-occurs, at least I know I have done everything I can to fight against it*'). These patients indicated that they want to 'just get it over with' and not postpone the operation. Since undergoing surgery remains the standard treatment after nCRT, and given that patients wanted to follow an established trajectory, choosing for surgery made more sense to them than choosing for an experimental treatment like active surveillance ('*To me, finishing a trajectory means taking the steps that must be followed, and surgery is the last step. If that is completed, then we can just go on with our lives*').

3.4.3 | Quality of life

Patients choosing for surgery were convinced they should not let the consequences of surgery hold them back in undergoing the procedure. In that sense, quality of life is subordinate to quantity of life: ('*Well, I think I just go through that very nasty dark tunnel for a while, but eventually there will be light at the end of the tunnel [...] Personally, I am not done with life, I still have things I want to do, I am not tired yet*').

TABLE 2 Results at T1 and T2 (3 and 12 months, respectively, after completion of neoadjuvant chemoradiotherapy) on quality of life, anxiety, coping and decisional regret

	Active surveillance		Surgery			
	M	*SD*	*M*	*SD*	*t*(df)	*P*
T1						
Quality of life						
EQ-5D-5L	0.95402	0.08	0.82102	0.13	$t(28.03) = -3.78$	.001
EQ-VAS	85.25	9.80	63.89	20.90	$t(23.56) = -3.96$	.001
Anxiety						
CWS	12.45	4.07	14.22	4.01	$t(35.7) = 1.35$	.18
STAI	16.31	3.97	18.50	6.67	$t(35) = 1.22$	.23
Coping						
TMSI: blunting	28.25	6.98	29.56	3.76	$t(30) = 0.66$	.51
TMSI: monitoring	27.01	8.64	22.94	7.49	$t(29.4) = -1.44$	.16
T2						
Quality of life						
EQ-5D-5L	0.9179	0.07	0.8624	0.13	$t(22.02) = -1.48$	.153
EQ-VAS	84.44	6.86	71.81	18.54	$t(19.03) = -2.55$	.02
Anxiety						
CWS	12.16	3.90	12.42	3.23	$t(28.9) = 0.19$	.85
STAI	16.5	4.69	16.13	5.19	$t(28.2) = -0.21$	.84
Coping						
TMSI: blunting	28.91	62.91	26.75	5.76	$t(23.4) = -1.28$	.21
TMSI: monitoring	24.00	6.91	24.56	7.46	$t(20.4) = 0.19$	.85
Decisional regret						
DRS	5.88	10.49	10.31	10.56	$t(1.21) = 31$	.24

3.4.4 | Reasons against choosing for active surveillance

Next to reasons to opt for surgery as mentioned above, patients mentioned specific reasons not to choose for active surveillance. The biggest disadvantages mentioned, were the repetitive diagnostic investigations which they believed to cause a lot of stress. ('*The insecurity of the recurring hospital visits is mentally really challenging, I really do not like that*'). By opting for active surveillance, they would continue to feel like a patient because they remain connected to the hospital. Also, active surveillance to their opinion was just a postponement of surgery, so they might as well do it now. Some patients also stated that active surveillance, as an alternative treatment, would make them feel like 'guinea pigs': ('*I choose for surgery because this research remains in its infancy, and it is too early to have an opinion for the long-term effects*').

3.5 | Shared factors

We found five more factors that influenced patients' treatment preferences, but did not necessary discriminate between patients opting for active surveillance or surgery. These should be considered as contributing factors that interact with the patient preferences mentioned in the model. An example is the way patients interpret information given by the professionals. If a doctor seems—according to the patient—enthusiastic about one of both treatment options, the patient is tended to opt for that specific treatment. This applies to both active surveillance and surgery.

Religion may provide support in dealing with cancer and the disease trajectory ahead, whether the patient opts for active surveillance or surgery. Religion was mostly considered as supportive for the difficult time to come, rather than being the leading motivation for the treatment decision.

Next, age can be confirming for the decision made. Interestingly it works for both ways: some patients stated that 'being young' causes them to choose active surveillance, other patients stated that 'being old' made them choose for active surveillance. The patients opting for surgery mainly referred to their age by stating they are still 'full of life' and just do not want to give up yet.

Past medical experiences did influence the decision in different ways. As one patient preferring active surveillance stated: ('*Actually, the brother of my husband passed away five years ago. He also underwent the surgery, involving the oesophagus [..] He died from the complications. So yes that played a role*'). It also works the other way, when positive medical experiences gave patients trust to opt for surgery.

Finally, external factors were included in the decisional process. For example, patients took into account that their decision might affect their professional careers ('*If I undergo surgery, and it takes one or two years to recover, it will cost me my job*').

3.6 | Questionnaires

Results of all questionnaires are presented in Table 2. Patients preferring standard surgery show a significant lower quality of life score at T1 (3 months after completion of nCRT) compared to those preferring active surveillance. No significant differences were found for anxiety and coping. With regard to decisional regret, we found that both groups showed low levels of regret, with no significant differences between the groups.

4 | DISCUSSION

Our study aimed to gain insight in the motivations behind patients' strong preferences to opt for either active surveillance or standard surgery after nCRT in their treatment of oesophageal cancer. We were unable to find differences between the groups when coping styles were measured using standard questionnaires about monitoring and blunting coping styles. However, in the qualitative analyses we did find a clear difference; patients with a strong preference for active surveillance tend to cope with the threat of cancer by confiding in their bodies and good outcomes; patients with a strong preference for standard surgery tend to cope by minimizing the uncertainty.

Patients preferring surgery did so because the threat of cancer leads to a pursuit of security. In contrast to the patients preferring active surveillance, they did not feel the threat was gone and did not feel peace in doing nothing. Their mind-set is one of 'active surviving' and 'taking one's live in own hands', as reflected by doing everything that is possible to survive (ie, surgery), regardless the impact on quality of life.

Patients preferring active surveillance felt good at that present moment and cope by drawing hope from the positive outcome of nCRT. Their line of reasoning is: 'Why should I undergo surgery, if no cancer is found after nCRT'. The possibility to skip surgery was seen as an opportunity to get on with life and enjoy it. However, a preference for active surveillance did not seem to be driven by negative feelings towards surgery. Although feelings of anxiety or reluctance towards surgery may be characterized by a general fear of the operation itself, the anaesthesia, the recovery, and health status after surgery, patients indicated that if necessary surgery would still be an option. Their mind-set of 'living in the present', is reflected by a pursuit to maintain quality of life.

These findings tie in with our quality of life data that showed a preference for active surveillance is associated with a higher quality of life at baseline. When someone experiences a high quality of life and realizes that surgery may adversely change that, one might be likely to opt for active surveillance.

We found no statistically significant differences in anxiety levels between patients opting for active surveillance and patients opting for surgery. However, other studies found that patients with early prostate cancer on active surveillance treatment are less anxious compared to patients on active treatment strategies.[22,23] Differences between these and our study might be related to the smaller sample size of the present study, especially as the differences between groups point in the same direction. Further, although the questionnaires on anxiety did not show a statistically significant difference, results from the qualitative analyses indeed revealed that patients opting for active surveillance display more trust, and thus less anxiety.

Patients did not refer to age as the decisive factor in their treatment preference. Nevertheless, the demographic data shows that patients opting for active surveillance are on average 10 years older. The literature reports about a negative correlation between age and acceptance of treatment side effects.[24] Following this, older patients would be less willing to tolerate severe side effects of surgery, which will negatively influence their quality of life.

We found (very) low levels of decisional regret in this sample, with no differences between the groups. Considering that all patients had a strong preference for their chosen treatment to begin with, a regret might be not be expected.

This is the first study to explore personal motives of oesophageal cancer patients in treatment decision-making. The generalizability of our findings is limited to (a) patients with strong preferences; (b) the setting of a randomized trial; (c) the condition that it is unclear whether active surveillance is noninferior to surgery. Having said that, if the outcome of the trial would show that active surveillance is noninferior, it is reasonable to assume that the line of reasoning of the patients included in the present study will be present in the future patient population. However, this needs to be confirmed by future research.

Our study contributes to a better understanding of what truly matters to oesophageal cancer patients when deciding between active surveillance or standard surgery after nCRT. Patient preferences for either treatment revealed as highly individualized and thus difficult to predict. To help healthcare professionals attune to the patients' needs, our study provides a model to identify patient treatment preferences wherein coping style and mind-set are determining factors.

AUTHOR CONTRIBUTIONS

Merel Hermus: Data curation; Formal analysis; Writing original draft; Writing - Reviewing and Editing; **Berend J. van der Wilk:** Conceptualization; Data curation; Writing - Reviewing and Editing; **Rebecca T. H. Chang:** Data curation; Formal analysis; Writing - Reviewing and Editing; **Gerlise Collee:** Data curation; Writing - Reviewing and Editing; **Bo J. Noordman:** Writing - Reviewing and Editing; **Peter-Paul L. O. Coene:** Resources; Writing - Reviewing and Editing; **Jan Willem T. Dekker:** Resources; Writing - Reviewing and Editing; **Henk H. Hartgrink:** Resources; Writing - Reviewing and Editing; **Joos Heisterkamp:** Resources; Writing - Reviewing and Editing; **Grard A. P. Nieuwenhuijzen:** Resources; Writing - Reviewing and Editing; **Camiel Rosman:** Resources; Writing - Reviewing and Editing; **Liesbeth Timmermans:** Conceptualization; Writing - Reviewing and Editing; Funding acquisition; **Bas P. L. Wijnhoven:** Resources; Writing - Reviewing and Editing; **Charlène J. van der Zijden:** Writing - Reviewing and Editing; **Jan J. Busschbach:** Conceptualization; Writing - Reviewing and Editing; **J. Jan B. van Lanschot:** Conceptualization; Writing - Reviewing and Editing; **Sjoerd M. Lagarde:** Conceptualization; Resources;

Writing - Reviewing and Editing; Funding acquisition; **Leonieke W. Kranenburg:** Conceptualization; Formal analysis; Writing - Reviewing and Editing; Supervision; Funding acquisition. The work reported in this article has been performed by the authors, unless clearly specified in the text.

CONFLICT OF INTEREST

The authors declare no conflicts of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of our study are available on request from the corresponding author.

ETHICS STATEMENT

The study was approved by the Erasmus MC Medical Ethical Committee (MEC-2018-1526). Informed consent has been obtained from all participants.

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How to cite this article: Hermus M, van der Wilk BJ, Chang RTH, et al. Patient preferences for active surveillance vs standard surgery after neoadjuvant chemoradiotherapy in oesophageal cancer treatment: The NOSANO-study. *Int J Cancer*. 2023;152(6):1183-1190. doi:10.1002/ijc.34327