Author’s response to reviews

Title: Treatment Selection of Early Stage Non-Small Cell Lung Cancer: The Role of the Patient in Clinical Decision Making

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Author’s response to reviews:

Dear editors, dear reviewers,

Thank you very much for careful reviewing our article and allowing us to explain and resolve the indistinct aspects in our manuscript. The comments of the reviewers were helpful to further improve the paper. All questions and arguments will be answered and commented on below.

Reviewer #1 (Jamie L Studts)

Comment 1: This study addressed some interesting and important questions regarding treatment decision making following an early stage lung cancer diagnosis. Several validated instruments were used to measure decision-relevant and outcome variables. However, it appeared that several ad hoc items were also included, and the psychometric foundation of these decision items was not provided. Solid imputation strategies were employed to deal with the challenge of a modest amount of missing data at baseline. While the study achieved a reasonable response rate for work conducted in this population, longitudinal analyses of the outcome data was hampered by non-response due to an aggressive disease with generally poor outcomes. The study concluded that additional work is needed to facilitate integration of shared decision making into thoracic oncology settings in order to achieve greater patient-centered care in this setting.
Answer 1: Thank you for this valuable comment. We agreed with the reviewer that it is important to provide the psychometric foundation of every question. However, there are not that many validated questionnaires for (lung) cancer patient to get an overview of their knowledge about cancer treatment of perceived understanding of information regarding their disease and treatment. Nevertheless, we used Control Preference Scale and Decisional Conflict Scale which showed nicely the amount of control the patients wanted when making health care decisions and whether they experienced decisional conflict.

Changes 1: No changes

Comment 2: The background information provided does not integrate previous decision making research in oncology and does not include previous literature exploring individuals diagnosed with lung cancer.

Answer 2: Thank you for this comment, it has improve the background section of our manuscript

Changes 2: Background section:

Shared decision making (SDM) is a process in which physician and patient work together in making a health decision after discussing the options, the benefits and harms, and considering the patients’ values, preferences, and circumstances [6, 7]. SDM is seen as the middle ground between informed choice, where the patient makes the decision based on information received from the physician, and traditional paternalistic decision making., where the physician makes the decision based on best available evidence [8, 9]. Patients who are active participants in the process of their care, for example asking questions, expressing their opinions and preferences, have better health outcomes, more knowledge regarding the disease and they are less anxious than patients who do not participate in the decision making [7, 10-12]. SDM supports patient to understand the disease and weigh advantages and disadvantages of treatment options in their own context, which will result in an informed treatment decision making with patients’ needs and values incorporated. Although SDM has gained increased awareness among the healthcare community, it has not been widely incorporated into routine clinical practice in lung cancer care. This can be explained by the fact that there is lack of familiarity with SDM [13, 14], and also because the care of lung cancer patient can be complex due to multiple treatment types over an extended period of time and often includes a guideline-drive treatment [15]. Furthermore, there are a number of factors that complicate the implementation of SDM in current clinical practice such as guideline based treatments, patient knowledge, time constrains and care settings [16] [17].

Comment 3: The manuscript provides substantial details on commonly used measures (e.g., decisional conflict scale, SF-36), but might benefit from additional details or examples of some of the ad hoc and less commonly used items pertaining to patient perspectives on the lung cancer treatment decision making process. In particular, it was not clear how analyses of the perceived lack of knowledge items were conducted or how the data was categorized.

Answer 3: Thank you for this valuable observation. We did not used advanced statistical methods to illustrate perceived lack of knowledge because this part was yes or no question.
Changes 3: Statistical Analysis

Aim 1 and 3 of this manuscript were analyzed using simple statistics by counting the ‘yes’ and ‘no’ answers. Components measured with 1-5 Likert-scale were not categorized.

Comment 4: In terms of study design, it may have been interesting for the study to explore decisional conflict or decision regret over time in addition to the SF-36 data. However, this is a minor point given the noted difficulty of obtaining surveys at 6 and 12 months from this population.

Answer 4: This is an interesting subject. As we describe in HRQoL we could not analyze the effect of time due to the low response rate at 6 and 12 months. The same is the case for decisional conflict or decision regret over time.

Changes 4: Decisional Conflict Scale

In the surgery group 32 and 19 patients were alive at 6 and 12 months without tumor progression, respectively. In the SBRT group this was 9 and 4 patients at 6 and 12 months, respectively. Due to the low response rates at 6 and 12 months we could not explore decisional conflict over time.

Comment 5: In the results section, it was not always clear what analyses were conducted or how data was categorized based on a lack of statistical information provided in the text. While a general description of proposed analyses was provided in the methods section, this was not sufficient to allow replication of the analyses.

Answer 5: Please see the answer and changes number 3.

Changes 5: Statistical Analysis

Aim 1 and 3 of this manuscript were analyzed using simple statistics by counting the ‘yes’ and ‘no’ answers. Components measured with 1-5 Likert-scale were not categorized.

Comment 6: To support the argument that decision conflict scores were clinically elevated, it would be helpful to provide comparison data from other samples. In the discussion section, the manuscript could address whether decisional conflict was higher in this sample lung cancer than other malignancies, and could this be a function of factors other than the actual decision making and patient-provider communication process? Might self-blame and stigma play a role in creating uncertainty about the treatment?

Answer 6: this has been a valuable comment, thank you.

Changes 6: Discussion section:
The same rates has been reported by patients treated for other type of cancer [53, 54]. Various factors can play a role in high levels of decisional conflict in cancer patients. First, most cancer patients want as much information as possible, however, they could be overloaded with information when it is offered ‘all at once’ or when the information is not provided to the patients’ family [55]. As we have illustrated in this study, an inadequate level of perceived information contributes the most to decisional conflict. Second, periodic assessment of cancer patient’s information requirements is also crucial, considering the complexity of cancer care. Finally………..

Comment 7: One comment in the discussion section noted that this population of patients suffers from emotional instability and is overloaded with disease information, but this is not supported with study data or referenced with data from other studies. There is data suggesting that individuals with lung cancer do commonly experience substantial distress, but it is not clear if individuals diagnosed with early stage disease commonly experience these similar levels of distress. Most data have over-sampled from individuals with later stage disease based on the fact that most patients present with later stage lung cancer.

Answer 7: From the consultation with our patients we concluded that our patients are often overloaded with information since lung cancer diagnosis is considered terminal by patients. We have added a reference regarding this topic from Jensen et al.

Changes 7: Reference added to this part of the manuscript (Jensen et al, The cancer information overload (CIO) scale: establishing predictive and discriminant validity. Patient Educ Couns 2014 Jan;94(1):90-6)

……….and could be overloaded with information about their disease[40]……………..

Reviewer #2 (Antoinette Wozniak)

Comment 1: Were patients all potential surgical candidates? It would seem that they would have to be if the 2 treatment options were discussed with them. This is unclear.

Answer 1: We included patients with stage I or II non-small cell lung cancer to get insight into current decision making from the perspective of both lung cancer patients treated with surgery or stereotactic radiotherapy. All patients were discussed in a multidisciplinary team meeting before the treatment, and in this meeting physicians recommended treatments that were suitable for the patient.

Changes 1: Method section:

All patients were discussed in a multidisciplinary team meeting before being accepted for treatment.
Comment 2: It seems incongruous that 80% of the patients felt that they had enough time to make a decision yet a fairly high number of patients still experienced decisional conflict. Do the authors have any explanation for this?

Answer 2: Thank you for this important comment, we agree that this seems incongruous. With decisional conflict scale we were able to objectively measure personal perceptions of uncertainty in choosing options, factors contributing to uncertainty and effective decision making. This scale illustrate how patients are informed and where the improvements are needed. The fact that 80% of patients felt that they had enough time to make a decision yet 40% of patients experienced decisional conflict. This underlines the gap between what the patient say and how the patient actually feel.

Changes 2: No changes

Comment 3: What was the compliance rate for the patients with regard to filling out the QoL forms?

Answer 3: As we have described in the method section (data collection, decisional conflict) we were not able to explore decisional conflict over time and the effect of time on quality of life due to low response rates at 6 and 12 months. In the surgery group 32 and 19 patients were alive at 6 and 12 months without tumor progression, respectively. In the SBRT group this was 9 and 4 patients at 6 and 12 months, respectively. The compliance rate was in the range of 90%.

Changes 3: No changes

Comment 4: Were parameters such as time the physician spent with the patient captured? Also did patients’ outcomes change dependent on the physician involved with the decision making or was that not captured?

Answer 4: This was a first step to get improved insight into current decision making from the perspective of early stage lung cancer patients. We did not capture the consultation time or change in outcome. This is a nice suggestion for the next observational studies.

Changes 4: No changes

Comment 5: It is mentioned in the discussion that it is important to discuss survival and prognosis with the patients. I think this needs to be explained better. There are studies to indicate that patients want their physician to be honest but they do not necessarily want to hear survival statistics. Discussions like this may come with subsequent visits but not necessarily when one is discussing treatment that might be potentially curative.

Answer 5: In our discussion we write that it is crucial to discuss survival and prognosis with the patient in a way that the patient will understand this information in order to avoid unrealistic high expectations as they often overestimate their life expectancy. As we describe in our discussion it challenging to know how much involvement a patients wants and needs, and the amount of control they prefer. This underlines shared decision making as well.
Changes 5: No changes. See discussion for the following section:

- It is crucial to discuss survival and prognosis with the patient in a way that the patient will understand this information because previous studies have shown that the cancer patients overestimate their life expectancy and probabilities of cure when compared to their physicians’ perspective [46-48]. This will lead to unrealistic high expectations about the medical treatment which is a common phenomenon in oncology patients [49, 50].

- One of the challenges of SDM is knowing how much involvement a patient wants and needs. It is even more difficult when patients vary in the amount of control that they prefer to have over the treatment decision-making at the time of diagnosis [26].

Comment 6: The authors outline some of the limitations of the trial and there are certainly many in this type of study. What kind of study design would they use in the future to further investigate shared decision making?

Answer 6: In order to improve literature and clinical practice of shared decision making in lung cancer patients we need more collaboration with Dutch hospitals, and with our colleagues abroad. Applying shared decision making in Dutch clinical practice is not very common due to little training in shared decision making and the presence of multidisciplinary team meetings. In The Netherlands the general practitioner redirects a patient with symptoms to a pulmonologist. If it appears to be lung cancer the patient will be presented during the weekly multidisciplinary team meeting and the recommendations of the multidisciplinary team will play an important role in treatment decision making. There is little room for applying shared decision making.

Changes 6: No changes

Thank you again very much for your time and valuable comments.

Best regards,

Sahar Mokhles