Patients’ confidence in treatment decisions for early stage non-small cell lung cancer (NSCLC)

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Abstract
Background
In early-stage Non-Small Cell Lung Cancer (NSCLC) patients, little is known about how to measure patient participation in Shared-Decision Making (SDM). We examined the psychometric properties and clinical acceptability of the Decision Self-Efficacy scale (DSE) in a cohort of patients undergoing to Stereotactic Ablative Radiotherapy (SABR) or Video-assisted Thoracoscopic Surgery (VATS) to capture patient involvement in treatment decisions.
Methods
In the context of a prospective longitudinal study (Life after Lung Cancer-LiLAC) involving 244 patients with early-stage NSCLC, 158 (64.7%) patients completed the DSE either on paper or electronically online prior to treatment with SABR or VATS pulmonary resection. DSE psychometric properties were examined using: principal components analysis of item properties and internal structure, and internal construct validity; we also performed a sensitivity analysis according to Karnofsky Performance Status, gender, age and treatment received (VATS or SABR) difference.
Results
Two subscales within the DSE were identified: the main factor accounting for almost 72% of the variance related to overcoming barriers to decision making (seven items) and a second factor explaining an additional 9.1% of the variance was related to information seeking processes (four items). We calculated a value of 0.96 for Cronbach’s alpha for the total DSE score, 0.94 for Factor 1 and 0.95 for Factor 2. DSE scores did not differ by gender ( p =0.37), between the two treatment groups (p=0.09) and between younger and older patients ( p =0.4). However, patients with a Karnofsky performance score (PS) >1 have a DSE mean of 73.8 (SD 26) compared to patients with a PS 0-1 who have a DSE mean of 85.8 (SD 20.3 p =0.002).
Conclusion
Findings provide preliminary evidence for the reliability and validity of the DSE questionnaire in this population. However, future studies are warranted to identify the most appropriate SDM tool for clinical practice in the lung cancer treatment field.
Introduction
The most effective treatment options for curative lung cancer are video assisted thoracoscopic (VATS) resection or stereotactic ablative body radiotherapy (SABR) for patients unfit for surgery. The treatment effectiveness is evaluated on survival data (1, 2) and presently there is little information about the effects of these treatments on patients’ quality of life (QOL)(3, 4). About 44% of patients diagnosed with lung cancer are aged 75 and over(5) and commonly have multiple comorbidities with 54% presenting with three or more(6) reducing their eligibility for surgery (6, 7). This makes the patients decision to proceed with one of these treatments more complex, especially for those patients at higher medical risk.

Although current treatment guidelines do not recommend SABR as first-line treatment for NSCLC moderate risk patients(1), multiple observational studies have suggested therapeutic equipoise exists between SABR and surgery in those patients with multiple comorbidities(8, 9). The lack of long term QoL data from these two treatments has highlighted the importance of understanding whether a truly informed “shared treatment decision” between patients and clinicians can be made. The quality of decision is highly dependent on the interaction in the doctor/patient consultation but also on the type of the information given.

Further, it is unclear what needs patients have when faced with a choice between treatment options: often improved knowledge about surgery does not necessarily translate into a more proactive attitude towards decision-making in lung cancer setting(10). It has been reported in lung cancer surgery, that many patients may wish to defer decisions about treatment to their medical team(10). On the other hand, professionals have to be confident they have the skills to best support patients in a shared-decision making. In a Dutch survey, 30% of surgeons stated they are not properly trained to implement SDM in clinical practice (11). Recent research in this field also confirmed that as result of the lack in standardized approach and deep understanding of SDM process, only 28.9% patients have been offered both treatment options for treatment of early-stage NSCLC(12).

Working towards patient and clinician shared decision-making (SDM) for treatment of curative NSCLC in clinical practice will require the development of guidelines and integration into existing decisional
algorithms. The last two decades have witnessed an increasing number of trials investigating the overall lack of concordance between physician and patient perceptions of the decisional context in many clinical areas including lung cancer management. The majority of these trials have shown that concerns and treatments strategies were insufficiently discussed between the patients and physicians(12, 13).

Although the area of SDM is an emerging research area, a number of measure have been developed to address patient informed, values-based choices (14). While, many different measures are available, the degree to which these measures are fully validated varies significantly. Currently, there is paucity of evidence assessing the views of patients with stage I NSCLC on aspects of shared decision-making (SDM).

To support proactively patients with cancer making decisions with clinicians (14), a first step is to explore factors associated with patient confidence in involvement in the SDM process. Self-efficacy is a psychological construct referring to an individual’s judgment of his/her confidence to carry out a specific task in order to produce a desired outcome (12). Furthermore, studies have showed self-efficacy has direct and indirect effect on QoL in patients with resected lung cancer(15).

Here we explore self-efficacy in the context of decision making using the decision self-efficacy scale (DSE) in a cohort of early stage NSCLC patients undergoing SABR or VATS anatomical lung resection by evaluating the psychometric validity and the sensitivity of the DSE scale.

Methods
1. Design and Sample
This design is a secondary analysis of data from a prospective longitudinal study of patients offered Stereotactic ablative radiotherapy (SABR) or Video-Assisted Thoracoscopic Surgery (VATS) for NSCLC in a large urban regional cancer centre (UK) between March 2017 to March 2018.

This study assesses the utility of a patient reported measure of decision making confidence carried out as part of the Life after Lung Cancer (LiLAC) study(4). LiLAC used validated Patient-reported outcome measures (PROMs) to describe the trajectory of Quality of Life (QoL) following VATS or SABR treatment. This study received ethical approval from NRES Yorkshire and the Humber- Leeds East
Research Ethics Committee (REC Ref: 16/YH/0407), and is registered in Clinicaltrial.gov database.

2. Procedures

All participants completed (online or on paper) a set of questionnaires before their treatment (between 1 to 20 days before) to capture their preoperative QoL and Decision efficacy. Patients at this point have been already allocated to a treatment group as per multi-disciplinary team meeting (MDT) decision.

The Decision Self-Efficacy Scale (DSE) measures self-confidence or belief in one’s ability to make informed decisions and participate in shared decision making with health professionals(16). It is a 11-item instrument with a five-point response scale ranging from 0 (not at all confident) to 4 (very confident). An example question is: ‘I understand the information enough to be able to make a choice’). The psychometric properties report a Cronbach alpha coefficient of 0.92, and the scale has been shown to be correlated with select subscales of the Decisional Conflict scale (DSC) [i.e., feeling informed (0.47) and supported (0.45) sub-scales] (17). Scores are linearly transformed: score of 0 means ‘extremely low self-efficacy’ and a score of 100 means ‘extremely high self-efficacy’. Missing values were imputed as recommended that if a participant has 1 missing item response per domain, this score is imputed using the mean of the participant’s other domain responses, although if ≥ 2 responses are missing, the domain score is treated as missing.

The following baseline demographic and clinical variables were collected: age, sex, forced expiratory volume in 1 second (FEV1) expressed in percentage of predicted value, Karnofsky performance score (PS), diffusing capacity of the lung for carbon monoxide (DLCO) expressed in percentage of predicted value, treatment type and smoking habit.

3. Analysis

The study sample demographic and clinical characteristics were summarised using descriptive statistics.

A principal component analysis (PCA) was used to examine the DSE structural validity. The minimum recommended sample size to conduct a PCA is 100 (18).

An exploratory (principal axis) factor analysis was conducted on the data set of 11 (N = 158 cases)
items using IBM SPSS version 24. In addition to the total variance explained, the scree plot, eigenvalues, and component loadings were assessed to verify the factor structure of DSE in this cohort. The factor analysis was performed using SPSS (IBM) Version 24.

We used STATA 15.0 (Stata Corp., College Station, TX, USA) statistical software to analyse (1) descriptive statistics, (2) floor and ceiling effects (% scores at the minimum and maximum values), and (3) internal reliability (Cronbach's alpha, corrected item-total correlations).

Although in the development studies Bunn (19) did not specify criteria for defining floor and ceiling effects, we employed the widely used N 15% of minimum/maximum scores cut-off(20). Following convention, we considered Cronbach's alpha's ≥ 0.70 to indicate acceptable internal consistency(21).

Feasibility was also assessed, in terms of proportion of missing data ("prefer not to answer” responses for the dataset overall and per item). We considered that < 5% missing data overall was acceptable, although we acknowledge there is no established consensus on this issue, with recommended criterion values ranging from 5–20% (22).

For highly related constructs, moderate to strong associations (r~ +/- 0.40 to 0.80) between these determinants and the factors of the DSE were expected (23).

Sensitivity of the module was assessed by means of known group differences according to the Performance Status, gender, age and treatment received (VATS or SABR).

As all the DSE variables were not normally distributed, they were compared across groups by the Mann–Whitney U test.

Results
Participant characteristics
A total of 244 patients consented to the study of which 158 (64.7%) returned the Decision Self-Efficacy Scale at baseline. Of these, 73 patients were treated using SABR, and 85 had VATS. We did not find any baseline difference between patients who completed the DSE (n = 158) and those who didn’t (N = 86) in terms of age (p:0.17), gender (p = 0.34) and PS > 1(p = 0.23). The baseline clinical characteristics of the participants included in this study are in listed in Table 1.

Table 1 Baseline demographic and clinical characteristics of participants N = 158.
Variable | All patients with DSE (n = 158) | SABR (n = 73) | Surgery (n = 85)
--- | --- | --- | ---
Treatment (surgery, %) | 85 (53.8) | | 
Gender (male, %) | 69 (43.6) | 26 (35.6) | 43 (50.5) 
Age (years, SD) | 72.4 (8.6) | 74.5 (9.3) | 70.5 (7.5) 
Comorbidity (yes,%)) | 135 (85.4) | 67 (91.7) | 68 (80) 
FEV1% (SD) | 83.5 (25.1) | 75.5 (27.4) | 89.2 (21.8) 
DLCO% (SD) | 77.6 (22.2) | 69.6 (22.8) | 83.5 (19.9) 
Current Smokers (n, %) | 34 (22.6%) | 19 (27.1) | 15 (18.7) 
PS 0-1 (n, %) | 104 (62.4) | 39 (53.4) | 15 (17.6) 
DSE (Mean, SD) | 81.7 (23) | 79.5 (23) | 83.6 (22.9) 

Results are expressed as mean and standard deviation (SD) for numeric variables and as count and percentages for categorical variables. FEV1: forced expiratory volume in one second; diffusing capacity of the lung for carbon monoxide (DLCO) expressed in percentage of predicted value, Karnofsky performance score (PS).

Mean value of the DSE was 81.7 (SD 23). In the Surgical group the mean score was 83.6 (SD 22.9) and in the SABR one was 79.5 (SD 23). DSE is the main score representing the overall efficacy in making the decision. Patients treated with SABR were older, with more comorbidities, lower FEV1 and DLCO values and higher PS. These differences were, however expected as the SABR treatment was indicated to those patients who were not physiologically fit for surgery.

Principal Components Analysis

A PCA analysis was conducted on the 11 items with oblique rotation (direct oblimin) as it was expected that the factors would not be independent. The Kaiser-Meyer-Olkin (KMO) measure verified sampling adequacy for the analysis (KMO = .91) well above the minimum criterion of .50, in addition all KMO values for individual items were ≥ .88 and Bartlett’s test of sphericity was also significant at p < .001. An initial analysis was run to obtain eigen values for each factor in the data. Two factors had Eigen values over Kaisers criterion of 1 and explained 81.2% of the variance. The screen plot depicted two inflections confirming Eigen values over 1. Table 2 shows the results of the PCA, suggesting that factor 1 (Items 5–11) represents overcoming barriers and factor 2 (1–4) represents information seeking.
Table 2
Summary of PCA results for the Decision self-efficacy scale (N = 158)

| Item on the DSE scale | Overcoming barriers | Information seeking |
|-----------------------|---------------------|---------------------|
| 5 Ask questions without feeling dumb | 1.01                |                     |
| 6. Express my concerns about each choice | 0.954               |                     |
| 7. Ask for advice | 0.83                |                     |
| 8. Figure out the choice that best suits me | 0.726               |                     |
| 9. Handle unwanted pressure from others in making my choice | 0.911               |                     |
| 10. Let the clinic team know what’s best for me | 0.754               |                     |
| 11. Delay my decision if I feel I need more time | 0.68                |                     |
| 1. Get the facts about medication choices available to me |                     | 0.999               |
| 2. Get the facts about the benefits of each choice |                     | 0.98                |
| 3. Get the facts about the benefits and risks of each choice |                     | 0.848               |
| 4. Understand the information enough to be able to make a choice |                     | 0.631               |

Eigen values: 7.91, 1.02, 9.13

% of variance: 71.96, 9.13

Construct validity

The decision self-efficacy scale performed well in terms of psychometrics in this sample (Table 3): we calculated a value of 0.96 for Cronbach’s alpha for the total DSE score, 0.94 for Factor1 and 0.95 for Factor2. The overall amount of missing data was < 5%, totalling just 1.5% of the dataset. However, a notable ceiling effects were apparent for the total DSE, Factor1 and Factor2, with > 15% of participants obtaining the maximum score (Table 3).

Table 3
Descriptive statistics, floor and ceiling effects and internal reliability for the DSE, F1 and F2

|         | N  | Mean (SD) | Floor effect (%min score) | Ceiling effect (%max score) |
|---------|----|-----------|---------------------------|-----------------------------|
| DSE     | 158| 81.7 (23) | 0.63%                     | 32.9%                       |
| Factor1 | 158| 82.7 (23.1)| 1.27%                     | 41.1%                       |
| Factor2 | 158| 80.7 (25.1)| 1.27%                     | 43%                         |

The items correlated significantly at p = 0.001. A determinant value of 2.09E-006 (above the necessary value of 0.00001) revealed that the level of collinearity would not be detrimental to the analysis therefore, no items were removed. The correlation matrix is provided in the Additional File 1.

Known-group differences
Group comparisons revealed no significant mean differences between the two treatment groups in terms of overall self-efficacy score (DSE): SABR 79.5, Surgery 83.6 ($p = 0.09$). There were no statistical differences between the two groups for each of the eleven items either (Table 4).

| Item                                                                 | Surgery (n = 85) | SABR (n = 73) | p value |
|----------------------------------------------------------------------|------------------|---------------|---------|
| DSE total score                                                     | 83.6 (22.9)      | 79.5 (23.1)   | 0.09    |
| **Factor 1**                                                        | 84.3 (24.1)      | 80.6 (23.8)   | 0.13    |
| **Factor 2**                                                        | 83.2 (23)        | 78.8 (26.2)   | 0.19    |
| 1. Get the facts about medication choices available to me           | 85.2 (23.5)      | 80.4 (26.1)   | 0.13    |
| 2. Get the facts about the benefits of each choice                  | 83.5 (26)        | 79.1 (26.0)   | 0.1     |
| 3. Get the facts about the benefits and risks of each choice        | 84.1 (25.8)      | 80.1 (27.3)   | 0.21    |
| 4. Understand the information enough to be able to make a choice    | 84.4 (26.1)      | 82.8 (24.6)   | 0.33    |
| 5. Ask questions without feeling dumb                               | 84.4 (30.8)      | 79.7 (30.8)   | 0.34    |
| 6. Express my concerns about each choice                            | 83.5 (26.8)      | 78 (30)       | 0.16    |
| 7. Ask for advice                                                   | 87 (26.8)        | 82.8 (26.3)   | 0.11    |
| 8. Figure out the choice that best suits me                         | 84.1 (23.7)      | 79.1 (28.8)   | 0.35    |
| 9. Handle unwanted pressure from others in making my choice         | 80.8 (29.2)      | 77.3 (30.6)   | 0.51    |
| 10. Let the clinic team know what's best for me                     | 83.8 (22)        | 77.7 (31)     | 0.5     |
| 11. Delay my decision if I feel I need more time                     | 79.1 (31.5)      | 76.7 (31.5)   | 0.88    |

* Factor 1 (Items 5–11) represents overcoming barriers and **factor 2 (1–4) represents information seeking.

Patients with the Karnofsky performance score (PS) $> 1$, less fit, reported less self-efficacy in making their decision during the preoperative period. Indeed, patients with PS $> 1$ have a DSE mean of 73.8 (SD 26) compared to patients with a PS 0–1 who have a DSE mean of 85.8 (SD 20.3 $p = 0.0024$). Furthermore, these patients were different on both subscales identified in the factor analysis: F1 ($PS > 1$: 76.1 vs PS 0–1: 85.9 $p = 0.0052$) and F2 ($PS > 1$: 171.6 V s PS 0–1: 85.4 $p < .001$)

No statistically significant differences between DSE scores for men and women were evident ($p = 0.37$). Male patients had a mean DSE value of 84.0 (SD 21.3) and female of 79.9 (SD 24.2). No difference between these groups was found by Factor 1 and Factor 2, $p = 0.41$ and $p = 0.62$ respectively.

Similarly, when comparing DSE among younger and older people (using the cut-off above and below the median value of 72 years) no statistically significant differences were found ($p = 0.4$). In particular, older people >
72 years had a DSE mean of 82.5 (SD 23.7) and younger people < 72 years 81 (SD 22.6). No difference between these groups was found by Factor1 and Factor2, p = 0.21 and p = 0.85 respectively.

Discussion
We aimed to explore the psychometric properties of the DSE in a cohort of patients undergoing VATS resection or SABR therapy for NSCLC. Our findings suggest the DSE is valid: the 11-item measure has good internal consistency (X of 0.96), with two independent subscales: one main factor explaining 72% of the variance on overcoming barriers to decision making (items 5-11) and the second factor explaining 9.1% of the variance (items 1-4) related to information acquisition. The developers recommendation for one scale is confirmed by the observed high internal consistency in our study, but we also recommend further exploration of the two factors in other populations, and when a more detailed understanding of the shared decision-making process is desired.

The observed significant ceiling effect (over 15% of responses) should be noted.
Almost 70% of the sample completed the decision self-efficacy scale demonstrating that the collection of this data is possible in this population. Furthermore, the overall proportion of missing data was low (1.5%), indicating that DSE was acceptable to patients.

There was no difference in efficacy with decision making by treatment type in this study. Patients with poor clinical performance status were more likely to be less confident in making their decision for treatment. We know patients who have a worse PS and limited functional capacity tend to have more difficulty tolerating rigorous cancer treatments, i.e. they have less favourable outcomes than fitter patients regardless of treatment type (24, 25). These patients did report less confidence in both seeking information from doctors and overcoming barriers aspects when making their best decision on treatment. One explanation can be that regardless of the treatment type when patients are less independent physically (as in those with higher PS score), they have more conflict or difficulty about the best treatment to meet their needs. In addition, performance status and cancer stage were significantly more influential than biological age when recommending treatments(26). In this sense, clinicians may tend to involve patients with a higher PS score less in the decision-making process, presumably with concerns about higher expected morbidity and mortality. In those cases, patients may perceive similarly less confidence in making that decision which is more “physician-driven”. Another possible explanation can be related to the fact that patients more compromised were never involved in discussions about possible treatment
alternative i.e. surgery: this may have influenced their efficacy in making the treatment decision as their opinion may have not played a role at all in all the course of the decision-making process.

The decision efficacy scale has previously been evaluated in patient populations referring to patient’s making decision regarding immunizations, screening, hormone replacement therapy, blood pression medications adherence(27–29) suggesting a good understanding and applicability of this questionnaire in field where difficult decisions need to be taken(17). For NSCLC patients it would be useful to investigate not only to have the self-efficacy but the ability to ask questions and clearly express their value and prediction of outcomes.

O’Connor developed within the same conceptual framework of the DSE a 16-item Decisional Conflict Scale rated on a Likert scale measuring the uncertainty in choosing options, modifiable factors contributing to uncertainty (information, values and social support)(17).

In situations where the evidence available is not clearly defined and the long-term benefits are still undetermined (as with SABR Vs VATS), the understanding of conflict in difficult decisions may be more relevant to help identifying patient’s needs and possibly develop tailored decision aids.

The implementation of decision aid in the field of early stage NSCLC has the potential also to streamline the pre-treatment pathway and reducing the referral to a second speciality opinion in these patients care. The decision conflict scale could be clinically more applicable to the conflictual choice between surgery and SABR especially for those borderline patients, where there is a clear equipoise in terms of risks and benefit an observation highlighted in the SABRTooth trial(30). In high risk patients where the surgery has not been completely excluded by objective parameters, the decision should be tailored and supported by the medical team but also validated decision aids, this has been successfully demonstrated in other specialities(31). It would also be important to investigate and measure the involvement in decision and the ability to access and understand information(32).

However, we must be aware that a good decision often doesn’t correspond to a good outcome: indicators of good decision making may include reduced uncertainty, improved knowledge, more realistic expectations, improved clarity of values and value congruence with the decision; reduced decision delay; improved adherence to the decision, and efficacy (17, 33). Understanding the latter, can have crucial clinical implications in the development of a decision aid and ultimately help people considering their options and making the best decision for them.

This study may have potential limitations:
We have a 67% of return rate. We cannot exclude that the inclusion of the other consented participants would have changed the results. Further investigation of its psychometric properties in samples which include a wider group of patients is advised.

We could not assess all aspects of validity. Instrument validation is often considered to be an ongoing process and future studies that include this measure could provide further more confirmatory information on the psychometric properties.

The study had a relatively small sample size, and was performed in a single centre. Certainly, it seems that the processes to choose between treatment types in cancer are similar, suggesting the same type of information about the risks and benefits and long-term consequences of both treatments should be presented equally by clinicians to support informed choice. Alternatively, it may be that this questionnaire is not as sensitive to the differences between the different types of choices as other measures, e.g. decisional conflict scale. Certainly, patients found it difficult to make a treatment choice, regardless of treatment type, suggesting a decision aid might be helpful for patients to reach a decision with more confidence. However, the questionnaire has not up till now been tested in a cancer population. Previously the DSE had been utilised with menopausal woman and psychiatric patients (16, 19), thus limiting the comparability of our findings.

Another limiting factor of our study design is that we collected the questionnaires after patients made their final decision; it may be that there are more patients who do not feel involved in their decision making earlier in the treatment pathways.

Conclusions

We demonstrated that the collection of decision efficacy questionnaire in a population of cancer patients facing difficult decision is feasible.

We provided evidence for the validity of the DSE as a 11-item measure with two main subscales one main factor related to overcoming barriers to decision making and the second relating to information acquisition.

Our results demonstrated that the DSE questionnaire discriminates between the low and high PS of patients. This confirms the importance to identify those patient subgroups which will benefit from programmes aimed to improve their participation in treatment decision-making contexts.

The conflict, more than the social and emotional component of the difficult-decision making may be more relevant when evaluating the routine data collection in complex clinical area like this one (34). This may help identify people with greater need of help and thus enable specific support in making decisions and will help in the future tailoring of specific decision aids.

Our study findings may also inform future investigations around decision making within complex care and the resources required to reliably collect information on SDM process in clinical practice.

Abbreviations

NSCLC: Non-Small Cell Lung Cancer; SDM: Shared-Decision Making; DSE: Decision Self-Efficacy scale; LILAC: Life after Lung Cancer; SABR: Stereotactic Ablative Radiotherapy, VATS: Video-assisted Thoracoscopic Surgery;
Declarations

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Authors’ contributions
CP, GV, and HB conceived the overall idea of the DSE part for the Lilac study and all authors designed the study.

PH, CP and ZR performed the statistical analyses. CP wrote the first draft of the manuscript. All revised the manuscript critically. All have given their final approval of the version to be published.

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Availability of data and materials
The data that support the findings of this study are available from Cecilia Pompili but restrictions apply to the availability of these data, which were used under license for the current study, and so are not publicly available. Data are however available from the authors upon reasonable request and with permission of Cecilia Pompili.

Ethics approval and consent to participate
This study received ethical approval from NRES Yorkshire and the Humber- Leeds East Research Ethics Committee (REC Ref: 16/YH/0407), and is registered in Clinicaltrial.gov database.

Consent for publication
Not applicable.

Competing interests
The authors declare that they have no competing interests. Professor Velikova reports personal fees from Roche, personal fees from Eisai, personal fees from Novartis, personal fees from Pfizer, grants from NIHR UK Government, grants from Breast Cancer NOW, grants from EORTC, outside the submitted work.

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