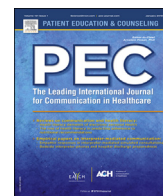




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A prospective cohort study of shared decision making in lung cancer diagnostics: Impact of using a patient decision aid

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ABSTRACT

Objective: The objective of this study was to describe the impact on patient-reported outcomes of introducing Shared Decision Making (SDM) and a Patient Decision Aid (PtDA) in the initial process of lung cancer diagnostics.

Methods: We conducted a prospective cohort study, where a control cohort was consulted according to usual clinical practice. After introducing SDM through a PtDA and training of the staff, the SDM cohort was enrolled in the study. All patients completed four questionnaires: the Decisional Conflict Scale (DCS) before and after the consultation, the CollaboRATE scale after the consultation, and the Decision Regret Scale (DRS).

Results: Patients exposed to SDM and a PtDA had significantly improved DCS scores after the consultation compared to the control group (a difference of 10.26, $p=0.0128$) and significantly lower DRS scores (a difference of 8.98, $p=0.0197$). Of the 82 control patients and 52 SDM patients 29% and 54%, respectively, gave the maximum score on the CollaboRATE scale (Pearson's χ^2 8.0946, $p=0.004$).

Conclusion: The use of SDM and a PtDA had significant positive impact on patient-reported outcomes.

Practice implications: Our results may encourage the increased uptake of SDM in the initial process of lung cancer diagnostics.

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1. Introduction

Lung cancer is a physically, socially, and psychologically devastating malignancy with a high incidence. Rapid and precise diagnosing and staging is fundamental [1,2] and fast-track lung cancer evaluation is therefore standard of care in many health care systems.

A fast-track lung cancer diagnostic process is mentally and physically enduring [3]. Typically, a patient will undergo CT scans, a PET-CT scan, biopsies, and endoscopies. None of these procedures are without risk of complications, which may be serious, require hospital admission, and even be fatal [4].

When patients are referred to fast-track lung cancer evaluation at our institution, a CT scan of the chest and abdomen is performed [5].

For most patients further evaluation to establish diagnosis and stage is typically advised without delay. However, in a significant number of patients lung cancer is not very likely but at the same time cannot be ruled out based on the CT scan and referral note. In this group of patients, it is not scientifically clear whether to recommend further diagnostic, invasive procedures with potential risks involved, arrange close follow-up with regular CT scans, or deselect further evaluation [6–8]. Guidelines have encouraged the use of SDM to engage patients in the decision on the intensity of the diagnostic process, but the practice is not consistent among pulmonologists [9]. We therefore aimed to test SDM in a systematic manner to guide patient engagement in a situation with only a small suspicion of lung cancer.

SDM is a clinical process in which clinicians and patients make appropriate health decisions together based on clinical evidence and patient preferences. SDM is developed for clinical situations with great ambiguity as well as severe consequences and has proven to facilitate patient involvement [10–16]. SDM may increase patient involvement by making the patient comfortable

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in taking active part in decision making in situations where there is more than one option and one is not clearly better than the other. Furthermore, SDM may help physicians respect the fact that patients value the potential benefits or harms of a certain option differently. One model of practicing SDM applying a patient decision aid (PtDA), initiates by making the patient aware that he/she is in a decision making situation and invite the patient and relatives to take part in the process. Options and patient values may then be clarified to facilitate deliberate decision making [17,18].

Patient decision aids are tools that can be developed to support the process of SDM. The central purpose of a PtDA is to help patients identify their preferences and make specific and conscious decisions among health care choices. A PtDA should clearly present evidence based, understandable options and facilitate the clarification of patient values [19]. The use of PtDAs has shown to improve patients' knowledge of options, make patients more clear about what matters to them, and to decrease their decisional conflict [13,14,20].

The objective of this study was to investigate whether the introduction of SDM and a PtDA could improve the degree of patient experienced decisional engagement and reduce the decisional conflict and regret in a high volume, fast-track lung cancer organization.

2. Methods

2.1. Design

We designed a prospective cohort study comparing an unexposed cohort with an exposed cohort. The study included two phases, a control baseline phase followed by a SDM phase. The intervention was the introduction of SDM and a PtDA, specifically developed for this clinical setting. The staff was trained in conducting SDM and using the PtDA after the control baseline and just before the SDM phase. The training took place as 8-h courses with 8–10 participants, doctors and nurses together. The main focus was on SDM principles, secondarily on the PtDA. During

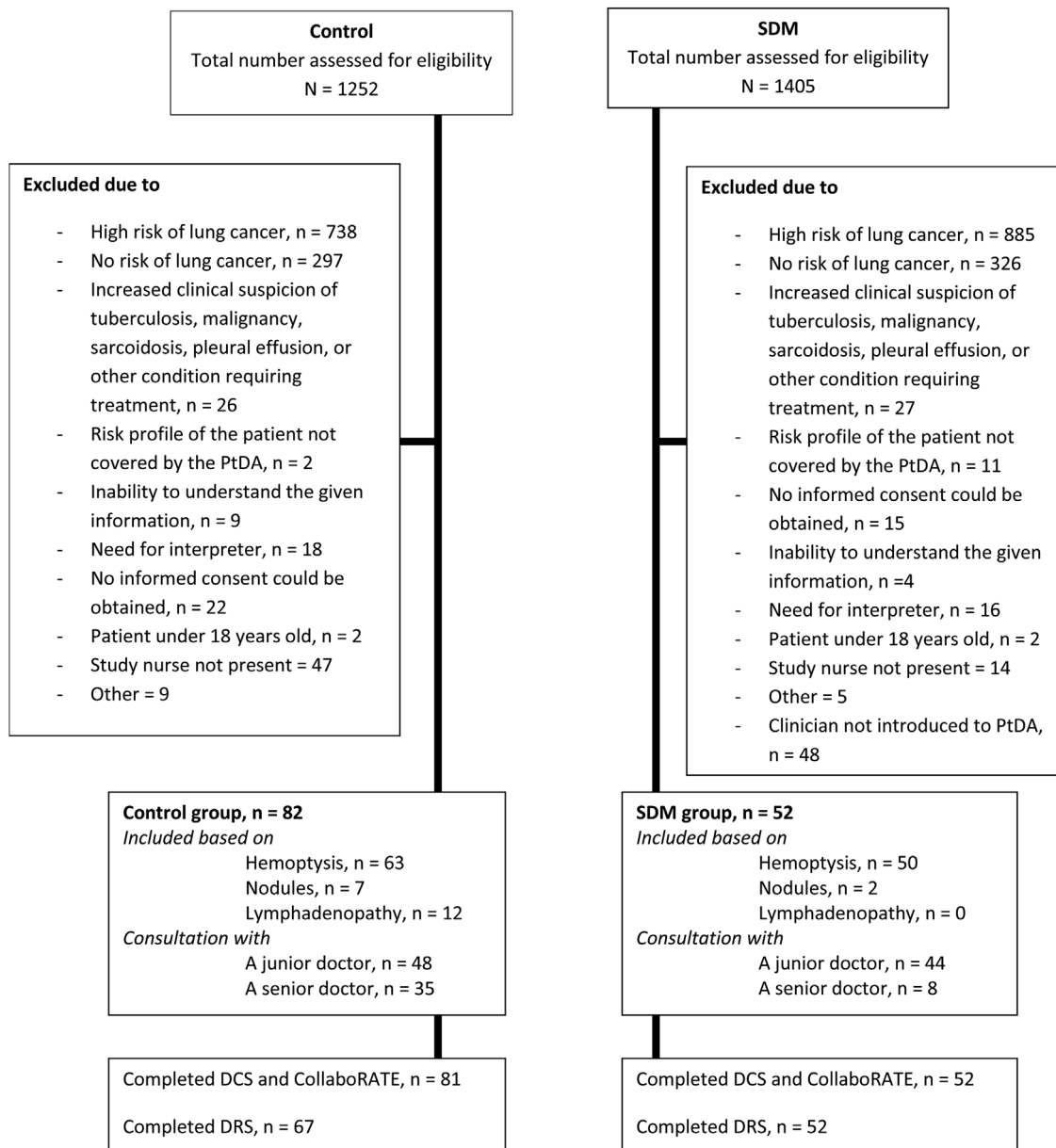


Fig. 1. Enrollment Process.

the SDM phase, new staff was training one-by-one by the study nurse for half an hour. After this introduction, SDM and the PtDA were tested in the daily clinical work at the Lung Cancer Organization during the SDM phase.

2.2. Setting

The fast-track Lung Cancer Organization at Vejle Hospital, Denmark, is a high volume center certified by the Organization of European Cancer with a population basis of around 600,000 people. Every year, 1600 patients are referred to the organization on suspicion of lung cancer and malignancy is confirmed in around 450. The Division of Respiratory Medicine coordinates the fast-track Lung Cancer Organization, which works closely together with many other specialties at the hospital, including radiology, nuclear medicine, oncology, radiation therapy, and pathology. On a yearly basis around 1000 bronchoscopies, 600 endoscopic ultrasound examinations of intrathoracic lymph nodes, 1000 CT guided lung biopsies, and 1500 PET-CT scans are conducted on suspicion of lung cancer.

The Center for Shared Decision Making at Vejle Hospital was established in 2014 and other PtDAs have been developed, clinically tested, and evaluated there, previously mostly in cooperation with the Department of Oncology [14].

2.3. CT conference

A CT conference takes place every morning in the Lung Cancer Organization with the senior doctor in charge, the junior doctor, and one or two specialist nurses present. At this meeting new CT scans are reviewed, and further evaluation is planned for each patient. Following the CT conference the patient is seen by the nurse and the junior or senior doctor that same day. In the SDM group the study nurse would have made a comment in the patient's record, if meeting the inclusion criteria based on the referral note and the CT scan. This note would guide the senior physician in the decision of whether or not to enroll the patient. For the control group, the study nurse enrolled patients according to the eligibility criteria.

2.4. Participants

Patients over 18 years of age were enrolled if they met one and only one of the following inclusion criteria: 1) one or two pulmonary nodule(s) of 8–10 mm, 2) hemoptysis and subsequent chest and abdomen CT scan with no apparent malignancy, or 3) mediastinal/hilar lymphadenopathy of 1–2 cm. The exclusion criteria were more than 2 nodules, growing nodules or growing lymphadenopathy, enhanced clinical suspicion of tuberculosis, malignancy, sarcoidosis, pleural effusion or other condition requiring treatment, risk profile of the patient not covered by the PtDA, if informed consent could not be obtained, e.g. due to inability to understand the given information or the need for translation.

The guidelines on the detection of lung cancer by the Danish Society of Respiratory Medicine were followed [21].

All patients gave oral and written consent to participate in the study, which was approved by the Region of Southern Denmark. Danish law does not require this kind of study to be approved by an ethics committee.

For further details on the enrollment process, please refer to Fig. 1.

2.5. The patient decision aid

The PtDA [22] used in this prospective cohort study was developed in 2016 in cooperation between the staff of the fast-track Lung Cancer Organization, the Center for Shared Decision

Making, and the Design School Kolding, Denmark [23]. The development and initial testing was a systematic process guided by the International Patient Decision Aid Standards (IPDAS) model [24,25].

In this study, the PtDA was used in the clinic as a conversation aid. Its design supports an approach of initially informing the patient that a choice needs to be made and asking the patient how much information he or she wants. The options were a minimum of information, a moderate amount of information, and most information possible. The next step sought to clarify patient values in this particular context offering two options: "Rapid clarification is more important to me than avoiding the complications involved in the diagnostic program" or "Avoiding the complications involved in the diagnostic program is more important to me than rapid clarification." Subsequently, different cards presented information about the options, including statistics and patient stories. Finally, the last question asked whether a decision was ready to be made in cooperation by the patient and clinician. Further information about the design and contents of the PtDA has been published elsewhere [18].

2.6. Questionnaires

We used the Danish translation of three international, validated questionnaires to investigate the patient-reported experience of SDM and to what extent the patients' decisional conflict and decisional regret were affected by SDM. Please refer to Fig. 2.

2.6.1. Decisional conflict scale

The Decisional Conflict Scale (DCS) is useful in elucidating patients' uncertainty and internal conflicts about a course of action, in this case whether to undergo further diagnostic work-up in a situation with a small risk of lung cancer.

The DCS has five subscales consisting of three or four questions concerning; uncertainty, information, values clarity, support, and effective decision. The uncertainty subscale reflects how sure the patient feels about the decision and how clear and easy the decision is to the patient. The information subscale indicates how well informed the patient feels in relation to options, benefits, risks, and side effects. The values clarity subscale concerns the degree to which the patient feels confident about what matters most in relation to benefits, potential risks, and side effects. The support subscale indicates whether the patient feels the choice can be made with support and without pressure from others. The effective decision subscale shows whether the decision reflects issues important to the patient, whether the patient is satisfied with the decision and feels an informed decision has been made and therefore expects to stay with it [26].

We used the first 12 items on the traditional 16-item DCS prior to the consultation and all 16 items after the consultation [27]. The DCS is a 5-point scale ranging from 1 (strongly agree) to 5 (strongly disagree). The total score and subscores were calculated according to the instructions in the DCS user manual. The scale ranges from 0 to 100; the higher the total score, the higher level of decisional conflict [26].

2.6.2. CollaboRATE

The CollaboRATE questionnaire is recognized as a valid and frugal 3-item measure of SDM focusing on the patient's sense of collaboration in decision making. The CollaboRATE scale is a 10 point scale ranging from 0 (no effort was made) to 9 (every effort was made) ([28]).

To elucidate the patient awareness of being invited to take part in a necessary decision making process we added the following question to the 3-item CollaboRATE scale; "Was it made clear to you that you were asked to take part in decision making?"

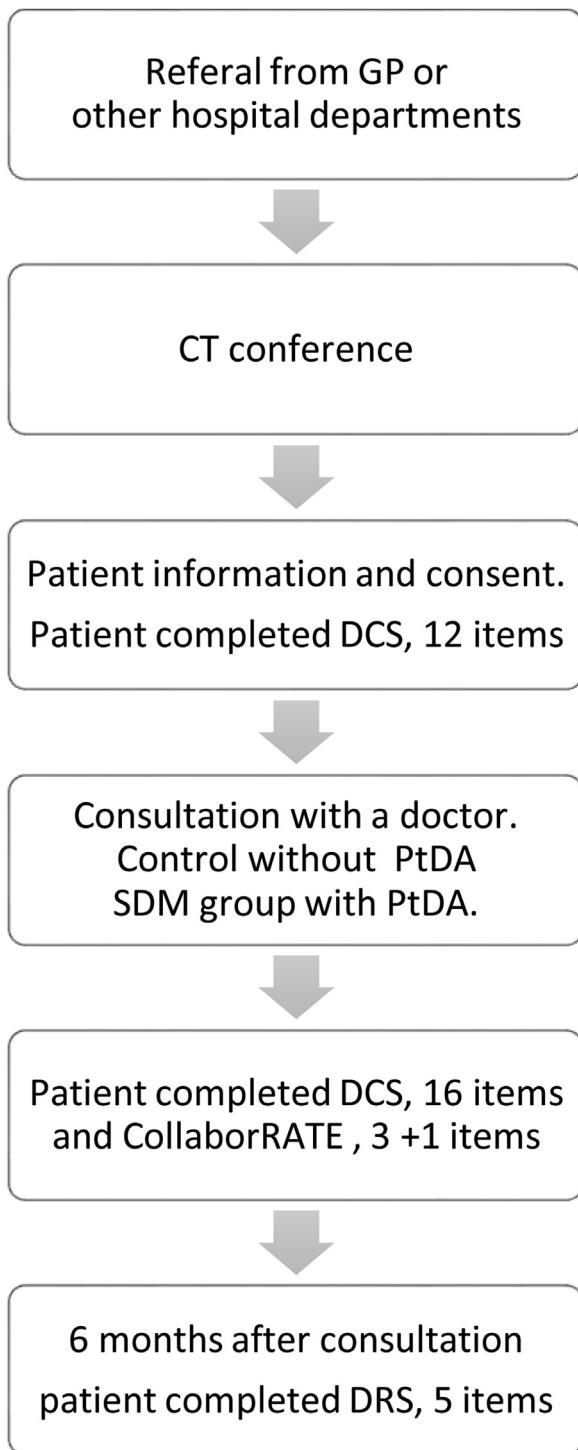


Fig. 2. Patient Flow.

A Danish version of CollaboRATE was used [29]. The four items in the CollaboRATE scale were analyzed with a mean score of all answers and a top score according to the generally accepted scoring method [30]. The top score equals the percentage of cases scoring 9 (full collaboration) in all four items.

2.6.3. Decision regret scale

The Decision Regret Scale (DRS) is a validated tool developed to measure the level of regret after health related decision making and has been used in different clinical settings and populations

[31,32]. The DRS consists of 5 items on a 5-point Likert scale ranging from 1 (strongly agree) to 5 (strongly disagree). The scale can be converted to a score from 1 to 100 with higher scores indicating more regret and a cut-off at 25 indicating no/mild regret. A Danish version of the DRS was used [27].

2.7. Statistical methods

The statistical work was performed in STATA/IC 15 (StataCorp LLC, College Station, Texas, USA). The DCS guideline [26], CollaboRATE guideline [30], and DRS guideline [32] were followed. Continuous measures were either presented as means with standard deviation (SD) or compared across groups using t tests. Categorical measures were compared across groups using chi square tests. Effect sizes were calculated using cohen's d. Linear regressions were used to adjust for potential differences in patient characteristics between the two cohorts.

3. Results

The first part of the cohort study (control group) took place from January 2017 to the end of June 2017. The second part (SDM group) was launched in June 2017 and recruited patients from October 2017 to the end of May 2018. Please refer to Table 1 for patient characteristics. There was no statistically significant difference between any of the patient characteristics in the two cohorts.

3.1. Decisional conflict score

No significant differences in the decisional conflict total score (DCS-score) or subscores before the consultation were found between the control group and the SDM group (see Table 2). However, as shown in Table 3, after the consultation the decreases in DCS-score, informed subscore and value subscore were significantly higher in the SDM group than in the control group.

Table 1
Baseline patient characteristics.

	Control, n=82	SDM, n=52
Age, mean (SD)	55 (15)	58 (16)
Gender (%)		
Male	55 (67)	34 (65)
Female	27 (33)	18 (35)
Education level (%)		
Public School	19 (23)	15 (29)
High School	3 (4)	0 (0)
Skilled worker	20 (24)	14 (27)
Lower sec. education	13 (16)	5 (10)
Upper sec. education	19 (23)	11 (21)
Academic education	7 (9)	4 (8)
Other	1 (1)	3 (6)
Marital status (%)		
Married / cohabitant	61 (74)	31 (60)
Single	16 (20)	16 (31)
Divorced	5 (6)	5 (10)
Work (%)		
Full time	38 (46)	21 (40)
Part time	6 (7)	3 (6)
Retired	33 (40)	24 (46)
Absent owing to illness	1 (1)	2 (4)
Unemployed	4 (5)	2 (4)
Risk factors		
Anticoagulant	16 (20)	17 (33)
CNS Disease	11 (13)	3 (6)
Heart Disease	15 (18)	8 (15)
Diabetes	4 (5)	4 (8)
Smoking, present or former	54 (67)	41 (79)
Asbestos	7 (10)	8 (24)

Table 2
DCS-score before consultation.

Decisional Conflict Scale before consultation	Control (95% CI)	SDM (95% CI)	Difference (95% CI)	P value, difference
Mean Total Score	56.69 (52.27 - 61.10)	60.78 (55.21 - 66.36)	-4.09 (-11.14 - 2.94)	0.2518
Mean Uncertainty Subscore	61.89 (56.67 - 67.11)	65.38 (58.27 - 72.48)	-3.49 (-12.00 - 5.14)	0.4225
Mean Informed Subscore	64.84 (59.33 - 70.35)	69.39 (62.61 - 76.20)	-4.55 (-13.25 - 4.14)	0.3022
Mean Value Subscore	60.46 (54.30 - 66.64)	64.60 (57.43 - 71.73)	-4.11 (-13.63 - 5.42)	0.3948
Mean Support Subscore	39.53 (35.73 - 43.34)	43.75 (38.26 - 49.24)	-4.22 (-10.63 - 2.20)	0.1955

Table 3
DCS-score after consultation.

Decisional Conflict Scale after consultation	Control (95% CI)	SDM (95% CI)	Difference (95% CI)	P value, difference
Mean Total Score	21.63 (18.33 - 24.92)	15.67 (11.55 - 19.79)	5.96 (0.74 - 11.18)	0.0255
Mean Uncertainty Subscore	22.33 (17.84 - 26.81)	16.5 (11.69 - 21.30)	5.83 (-0.91 - 12.56)	0.0895
Mean Informed Subscore	25.1 (20.96 - 29.24)	12.02 (8.79 - 15.25)	13.08 (7.35 - 18.82)	< 10 ⁻⁴
Mean Value Subscore	27.99 (23.26 - 32.71)	16.18 (11.70 - 20.67)	11.80 (5.0 - 18.66)	0.0009
Mean Support Subscore	15.22 (11.69 - 18.75)	13.46 (9.45 - 17.47)	1.76 (-3.64 - 7.17)	0.5199
Mean Effective Decision Subscore	18.53 (14.82 - 22.24)	13.00 (8.50 - 17.50)	2.95 (-0.30 - 11.36)	0.0627

In the control group the DCS-score changed from 56.69 before the consultation to 21.63 after the consultation (mean decline 34.86, 95% CI 29.74–39.97, $p < 0.001$). In the SDM group the DCS-score changed from 60.78 before to 15.67 after the consultation (mean decline 45.12, 95% CI 38.85–51.38, $p < 0.001$). Thus, it appears that the mean decline was 34.86 in the control group and 45.12 in the SDM group, a significant difference of 10.26 (95% CI 18.3 - 2.21, $p = 0.0128$).

Comparing the DCS-scores after the consultation in the control and SDM group an effect size of 0.40 (95% CI 0.05 - 0.75) was found.

3.2. Decisional conflict subscores

In the control group the informed subscore changed from 64.41 before the consultation to 25.1 after the consultation (mean decline 39.31, 95% CI 33.12–45.49, $p < 0.001$). In the SDM group the informed subscore changed from 69.39 before to 12.02 after the consultation (mean decline 57.38, 95% CI 50.55–64.20, $p < 0.001$). The mean decline in the informed subscore was 39.31 in the control group and 57.38 in the SDM group, a significant difference of 18.07 (95% CI 8.70–27.44, $p = 0.002$).

An effect size of 0.80 (95% CI 0.44–1.16) was found when comparing informed subscore after the consultation in the control and SDM group.

The value subscore changed from 59.98 before the consultation to 27.99 after the consultation (mean decline 31.99, 95% CI 25.24–38.74, $p < 0.001$) in the control group. In the SDM group the value subscore changed from 64.60 before to 16.18 after the consultation (mean decline 48.39, 95% CI 39.72–57.06, $p < 0.001$). With a mean decline in the value subscore of 31.99 in the control group and 48.39 in the SDM group, the difference between them was significant at 16.40 (95% CI 27.21 - 5.59, $p = 0.0032$).

The effect size was 0.61 (95% CI 0.25 - 0.96) for the value subscore after the consultation when comparing the control and SDM group.

For the uncertainty subscore and the support subscore the declines in score after the consultation were larger in the SDM group than in the control group but the difference was not significant. No significant effect sizes were found for the uncertainty or support subscores.

A multiple linear regression model was conducted including the two groups, the scores before and after the consultation, and the patient characteristics listed in Table 1. No patient characteristic were found to influence the decisional conflict scores.

3.3. CollaboRATE

A significant difference was found between the control and SDM groups in relation to the mean and top scores, showing more patient engagement in the SDM group. The mean CollaboRATE score in the control and SDM groups were 7.36 (95% CI 6.96–7.75) and 8.46 (95% CI 8.27–8.66), respectively, with a difference between the two groups at 1.1 (95% CI 1.62 - 0.60, $p < 0.001$). A multiple linear regression model including the two groups, the mean CollaboRATE score and all patient characteristics in Table 1 showed no influence of patient characteristics on the mean CollaboRATE score.

The top score by definition is calculated as a percentage. In the control group 29% of the 82 patients reported a full CollaboRATE top score after the consultation, whereas in the SDM group this was the case in 54% of the 52 patients (Pearson's χ^2 8.0946, $p = 0.004$). None of the patient characteristic presented in Table 1 were found to influence the CollaboRATE score.

3.4. Decisional regret score

The control group had a mean DRS score of 26.19 (95% CI 21.08–31.30) and the SDM group a mean score of 17.21 (95% CI 11.63–22.79). The difference of 8.98 (95% CI 1.66–17.54, $p = 0.0197$) indicates significantly less decisional regret in the SDM group.

We also investigated whether the DRS score of the patients who chose not to be examined further was significantly different from that of patients, who underwent further examination. In the control and SDM groups 33 out of 82 (40%) and 31 out of 52 (60%), respectively, chose not to undergo further examination (Pearson's χ^2 4.7860, $p=0.029$). Twenty-six of the 33 patients in the control group not undergoing further examination completed the decisional regret questionnaire; in the SDM group all the patients not undergoing further examination completed the questionnaire.

Inspired by others [33] a DRS score cut-off at 25 points divided the patients not undergoing further examination into two groups, i.e. scores below and above 25 were categorized as no/mild regret and high-level regret, respectively. In the control group 65% (17 of 26 patients) had no/mild regret and in the SDM group the fraction was 90% (28 of 31 patients) (Pearson's χ^2 5.2910, $p=0.021$).

For those who chose to undergo further examination no significant change in decisional regret was found between the control and SDM groups (Pearson χ^2 0.2866, $p=0.592$).

4. Discussion and conclusion

4.1. Discussion

The objective of this paper was to investigate whether the introduction of SDM and a PtDA could improve the degree of patient experienced decisional engagement, conflict, and regret in a high volume, fast-track lung cancer diagnostics organization.

The concept of SDM has been known and continuously improved for many years. SDM originates from the idea of involving the patient as opposed to strict paternalistic medical practice [16]. Politically, a growing interest in SDM is seen internationally [34–37] as well as in Denmark [38,39]. Most likely, many clinicians practice elements of SDM when communicating with patients, as they are aware that clear communication is crucial to engage patients in their treatment and improve patient compliance. However, studies show that clinicians do not engage their patients as much as the patients want them to [37,40,41], possibly because patient engagement in a busy hospital environment can be challenging despite every good intention. With its systematic approach SDM may help clinicians engage their patients to ensure that decisions made are based on patient preference in addition to evidence based information. Increased scientific proof of the impact of SDM may facilitate and support an enhanced effort and willingness among clinicians to implement SDM to a higher degree.

4.1.1. Decisional conflict

We found that patients in the SDM group had larger declines in DCS scores compared to the control group. For the total DCS scale a medium effect size was found. This may show that the use of SDM and a PtDA in our study has made the patients feel more certain about the decision made. Others have found similar effects when comparing SDM with usual care [42].

The decrease in the informed subscore and the value subscore was more extensive in the SDM group than in the control group. For both the informed and value subscores large effect sizes were found. This may indicate that patient values played a more central part of the consultation and hence the decision made in the SDM group. Also it seems that the conduct of SDM and use of a PtDA in our study helped the clinician deliver the information and the patient better understand the information given. Earlier results, including a Cochrane review of 105 articles on the effect of decision aids compared to usual care, also found that the use of decision aids makes people feel better informed and more clear about their values [13,14,43].

4.1.2. Patient engagement

We found a higher level of patient engagement in decision making in the SDM group measured on the CollaboRATE 4-item scale, indicated by significantly higher mean and top scores compared to the control group. It is, however, important to adjust the information and the degree of patient involvement to the specific patient. Not all patients wish to take part in decision making but rather expect and wish the doctor to make decisions for them [44]. A Danish survey has shown that most patients, but not all, wish to take part in the decision making process when evaluated for malignancy [45]. Therefore, SDM should incorporate questions to clarify the amount of information wanted and to which degree the patient actually wishes to participate in the decision making process. The design of our PtDA supports this approach to SDM.

4.1.3. Decision regret

Six months after the consultation the patients completed the 5-items DRS with a significantly lower score in the SDM group. Also, in the subgroup of patients not undergoing further examination the DSR scores were significantly lower in the SDM group than in the control group.

Others have found similar improvements in DRS when comparing the use of SDM [46] and a PtDA [47] with usual practice. A systematic review of regret after surgical treatment found that patients involved in the decision making prior to surgery felt less regret after the operation [48]. However, a one-year follow-up investigating the effect of including an online PtDA on the choice of prostate cancer treatment found no difference in decisional regret between patients exposed to the decision aid and the controls [49]. These diverging findings may reflect different ways of studying the impacts of SDM and PtDAs. For instance, the results of completing a DRS one year after the use of an online PtDA may not be comparable with those obtained six months after using a PtDA in a consultation. Therefore, direct comparison between studies should be done with caution.

We find a PtDA an important facilitator in the clinical process of SDM. So far, most PtDAs have been investigated as a means of preparation for the consultation. It has not yet been possible to conclude on the impact on patient-reported outcomes by using a PtDA during or before the consultation, although five small recent studies showed enhanced SDM by the use of PtDAs during the consultation [14]. Our study may contribute to mending the gap in the knowledge on PtDAs used during the consultation.

This study has several limitations. Due to reorganization in the Lung Cancer Organization during the summer and early autumn of 2017, enrollment in the SDM group was initially slow. Furthermore, 48 patients were excluded due to the clinician not having been introduced to SDM, which highlights the importance of training the staff. Although these factors led to fewer patients included in the SDM group, significant differences were found as described above.

For practical reasons the study nurse enrolled patients in the control cohort according to the eligibility criteria whereas in the SDM cohort, final enrollment was to be accepted by the senior doctor. To lower the impact of these diverging enrollment processes, the same study nurse wrote a note in the patient record during the SDM phase, if the patient met the inclusion criteria.

The patients were mainly included on the basis of hemoptysis, which was especially the case in the SDM group. Consequently, the results may not reflect the impact of SDM and a PtDA on patients referred due to lymphadenopathy or nodules, although similar impact on the two groups of patients seems likely.

In the control group 14 patients did not complete the DRS. We do not know if these patients had more regret than those who did

complete the DRS. Thus, our conclusions on decision regret should be interpreted with care.

A randomized controlled trial would have been ideal, but we were concerned that the approach to patients in the control group would have been influenced, since blinding of the physician would not be possible due to the nature of SDM. By letting the control phase run first, we hoped to minimize any influence of SDM on the control phase.

4.2. Conclusion

At the high volume, fast-track Lung Cancer Organization, Vejle Hospital, the implementation of SDM and a tailored PtDA significantly lowered the decisional conflict and regret of the patients. A significant increase in patient engagement in clinical decision making was also found. Since this paper describes a prospective cohort study, our results may have been affected by other changes during the study period. Our results may ideally be tested in future randomized clinical trials.

4.3. Practice implications

This clinical testing of SDM supported by the use of a PtDA during consultation has demonstrated positive effects on patient-reported outcomes. This study may therefore encourage clinicians to implement SDM into clinical practice. Future studies could focus on barriers and facilitators of implementation of SDM into daily clinical practice. Also, future studies may test SDM in a larger scale and, if possible, in randomized trials.

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Conflict of interest

The authors declare that there is no conflict of interest.

CRediT authorship contribution statement

Stine R Søndergaard: Formal analysis, Writing - original draft, Visualization. **Poul Henning Madsen:** Conceptualization, Methodology, Resources, Supervision. **Ole Hilberg:** Supervision, Funding acquisition. **Karina M Jensen:** Investigation. **Karina Olling:** Methodology, Writing - original draft, Investigation, Project administration. **Karina D Steffensen:** Methodology, Supervision, Funding acquisition.

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Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:<https://doi.org/10.1016/j.pec.2019.05.018>.

References

- [1] American Cancer Society <https://www.cancer.org/cancer/non-small-cell-lung-cancer/about/key-statistics.html>.
- [2] Eurostat, Cancer statistics - specific cancers, (2018) . Date accessed 29th of October 2018 https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Cancer_statistics_-_specific_cancers#Lung_cancer.
- [3] L.M. Aggestrup, M.S. Hestbech, V. Siersma, J.H. Pedersen, J. Brodersen, Psychosocial consequences of allocation to lung cancer screening: a randomised controlled trial, *BMJ Open* 2 (2) (2012) 1–9.
- [4] E.O. Leiten, E.M.H. Martinsen, P.S. Bakke, T.M.L. Eagan, R. Gronseth, Complications and discomfort of bronchoscopy: a systematic review, *Eur. Clin. Respir. J.* 3 (2016) 33324.
- [5] National Institute for Health and Care Excellence, Diagnosis and staging of lung cancer. [Internet]. [cited 2018 Oct 29]. Available from: <https://pathways.nice.org.uk/pathways/lung-cancer#path=view%3A/pathways/lung-cancer/diagnosis-and-staging-of-lung-cancer.xml&content=view-index>.
- [6] B. Hirschberg, I. Biran, M. Glazer, M.R. Kramer, Hemoptysis: etiology, evaluation, and outcome in a tertiary referral hospital, *Chest* 112 (August (2)) (1997) 440–444.
- [7] M. Evison, P.A.J.J. Crosbie, J. Morris, J. Martin, P.V. Barber, R. Booton, A study of patients with isolated mediastinal and hilar lymphadenopathy undergoing EBUS-TBNA, *BMJ Open Respir. Res.* 1 (1) (2014) 11–13.
- [8] A. McWilliams, M.C. Tammemagi, J.R. Mayo, H. Roberts, G. Liu, K. Soghrati, et al., Probability of Cancer in pulmonary nodules detected on first screening CT, *N. Engl. J. Med.* 369 (10) (2013) 910–919, doi:<http://dx.doi.org/10.1056/NEJMoa1214726> Available from [Internet].
- [9] R.S. Wiener, C.G. Slatore, C. Gillespie, J.A. Clark, Pulmonologists' reported use of guidelines and shared decision-making in evaluation of pulmonary nodules a qualitative study, *Chest* 148 (6) (2015) 1415–1421.
- [10] A. Coulter, Patient engagement-what works? *J. Ambul. Care Manage.* 35 (2) (2012) 80–89.
- [11] A. Coulter, A. Collins, DECISION-MAKING A REALITY No decision about me, without me.
- [12] M. Victor, M.D. Montori, MSc, Marleen Kunneman, PhD, P. Juan, M.D. Brito, Ms, Shared decision making and improving health care the answer is not in, *JAMA - J. Am. Med. Assoc.* 318 (7) (2017) 617–618.
- [13] K. McAlpine, K.B. Lewis, L.J. Trevena, D. Stacey, What is the effectiveness of patient decision aids for cancer-related decisions? A systematic review subanalysis, *JCO Clin. Cancer Inform.* (November (2)) (2018) 1–13.
- [14] D. Stacey, F. Légaré, K.B. Lewis, Patient decision aids to engage adults in treatment or screening decisions, *JAMA - J. Am. Med. Assoc.* 318 (7) (2017) 657–658.
- [15] K.D. Steffensen, M. Vinter, D. Crüger, K. Dankl, A. Coulter, B. Stuart, et al., Lessons in integrating shared decision-making into cancer care, *J. Oncol. Pract.* [Internet] 14 (April (4)) (2018) 229–235, doi:<http://dx.doi.org/10.1200/JOP.18.00019> Available from:.
- [16] F. Légaré, P. Thompson-Leduc, Twelve myths about shared decision making, *Patient Educ. Couns.* 96 (3) (2014) 281–286.
- [17] G. Elwyn, D. Frosch, R. Thomson, N. Joseph-Williams, A. Lloyd, P. Kinnersley, et al., Shared decision making: a model for clinical practice, *J. Gen. Intern. Med.* 27 (10) (2012) 1361–1367.
- [18] N. Joseph-Williams, A. Lloyd, A. Edwards, L. Stobbart, D. Tomson, S. Macphail, et al., Implementing shared decision making in the NHS: lessons from the MAGIC programme, *BMJ* 357 (April) (2017) j1744.
- [19] K.R. Sepucha, P. Abhyankar, A.S. Hoffman, H.L. Bekker, A. LeBlanc, C.A. Levin, et al., Standards for UNiversal reporting of patient Decision Aid Evaluation studies: the development of SUNDAE Checklist, *BMJ Qual. Saf.* [Internet] (December) (2017), doi:<http://dx.doi.org/10.1136/bmjqs-2017-006986>. Available from:.
- [20] G. Elwyn, A. O'Connor, D. Stacey, R. Volk, A. Edwards, A. Coulter, Developing a quality criteria framework for patient decision aids: online international Delphi consensus process, *Br. Med. J.* 333 (7565) (2006) 417–419.
- [21] T. Riis Rasmussen, et al., Danish Lung Cancer group. Clinical Guidelines. Lung Cancer - Visitation, Diagnosis, Staging Available from: (2018) , pp. 0–74. <http://lungcancer.dk/documents/CB1EF9C7-8DE3-4F1F-88D8-7CDA8D9CEB27.pdf>.
- [22] V.-L. Hospital, Shared Decision Making in Lung Cancer Diagnostic Organization, (2019) . Date Accessed: 22.01.2019. 2018. <http://www.cffb.dk/projekter/projekt-1/>.
- [23] K. Steffensen, K. Dankl, Shared decision making: empathic encounters between design and healthcare, P. Desmet, S. Fokkinga, G. Ludden, N. Cila, H. van Zuthem (Eds.), Proceedings of the 10th International Conference on Design & Emotion: Celebration & Contemplation (2016) 80–89 Sep 1.
- [24] K. Olling, T. Bechmann, P.H. Madsen, E.H. Jakobsen, D.B. Toftdahl, O.Hilberg, A. Coulter, K. Steffensen, Development of a patient decision aid template for use in different clinical setting, *Eur. J. Pers. Centered Health* 7 (1) In Press.
- [25] A. Coulter, D. Stilwell, J. Kryworuchko, P.D. Mullen, C.J. Ng, T. Van Der Weijden, A systematic development process for patient decision aids, *BMC Med. Inform. Decis. Mak.* 13 (SUPPL. 2) (2013) S2. Available from: [Internet]. <http://www.biomedcentral.com/1472-6947/13/S2/S2>.
- [26] A.M. O'connor, Validation of a decisional conflict scale, *Med. Decis. Making* 15 (1) (1995) 25–30.
- [27] The Patient Decision Aids Research Group, The Ottawa Hospital, 2018. Date Accessed: 29th of October https://decisionaid.ohri.ca/docs/develop/Tools/Regret_Scale_Danish.pdf.

- [28] P.J. Barr, R. Thompson, T. Walsh, S.W. Grande, E.M. Ozanne, G. Elwyn, The psychometric properties of collaborate: a fast and frugal patient-reported measure of the shared decision-making process, *J. Med. Internet Res.* 16 (1) (2014) 1–14.
- [29] CollaboRATE Danish Version, (2016) . Date accessed 29th of October 2018 <http://www.collaboratescore.org/collaborate.html>.
- [30] G. Elwyn, Scoring collaboRATE [Internet]. [cited 2018 Oct 29]. Available from: (2019) . <http://www.glynelwyn.com/scoring-collaborate.html>.
- [31] M.M. Becerra Perez, M. Menear, J.C. Brehaut, F. Legare, Extent and predictors of decision regret about health care decisions: a systematic review, *Med. Decis. Making* 36 (August (6)) (2016) 777–790.
- [32] J.C. Brehaut, A.M. O'Connor, T.J. Wood, T.F. Hack, L. Siminoff, E. Gordon, et al., Validation of a decision regret scale, *Med. Decis. Making* 23 (4) (2003) 281–292.
- [33] M.M. Becerra-Perez, M. Menear, S. Turcotte, M. Labrecque, F. Légaré, More primary care patients regret health decisions if they experienced decisional conflict in the consultation: a secondary analysis of a multicenter descriptive study, *BMC Fam. Pract.* 17 (1) (2016) 1–11, doi:<http://dx.doi.org/10.1186/s12875-016-0558-0> Available from: [Internet].
- [34] Secretary of State for Health U, Equity and excellence: Liberating the NHS (White Paper), The Stationery Office. Secretary of State for Health, UK, 2010. Available from: [Internet] http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_117353.
- [35] C. Bieber, K. Gschwendtner, N. Muller, W. Eich, [Shared Decision making (SDM) - Patient and Physician as a Team], *Psychother. Psychosom. Med. Psychol.* 66 (May (5)) (2016) 195–207.
- [36] Senate and House of Representatives, Public Law 111-148, The Patient Protection and Affordable Care Act. Washington, United States of America, (2010) , pp. 1–906. Available from: [Internet] <http://scholar.google.com/scholar?hl=en&btnG=Search&q=intitle:Public+Law+111+148#0>.
- [37] K.L. Kehl, M.B. Landrum, N.K. Arora, P.A. Ganz, M. van Ryn, J.W. Mack, et al., Association of actual and preferred decision roles with patient-reported quality of care: shared decision making in Cancer care, *JAMA Oncol.* 1 (April (1)) (2015) 50–58.
- [38] The Danish Ministry of Health and Prevention, Nationalt Kvalitetsprogram for Sundhedsområdet 2015 - 2018, (2015) , pp. 1–16 (April).
- [39] K. Dahl Steffensen, V. Hjelholt Baker, M.M. Vinter, Implementing shared decision making in Denmark: first steps and future focus areas, *Z. Evid. Fortbild Qual. Gesundheitswes* 123–124 (June) (2017) 36–40.
- [40] Danish Cancer Society, Kræftpatienters behov og oplevelser med sundhedsvæsenet under udredning og behandling, (2017) .
- [41] J.D. Tariman, D.L. Berry, B. Cochrane, A. Doorenbos, K. Schepp, Preferred and actual participation roles during health care decision making in persons with cancer: a systematic review, *Ann. Oncol.* 21 (June (6)) (2010) 1145–1151.
- [42] M. Bergeron, A.L. Duggins, A.P. Cohen, K. Tiemeyer, L. Mullen, J. Crisalli, et al., A shared decision-making tool for obstructive sleep apnea without tonsillar hypertrophy: a randomized controlled trial, *Laryngoscope* 128 (April (4)) (2018) 1007–1015.
- [43] T.A. Trikalinos, L.S. Wieland, G.P. Adam, A. Zgodic, E.E. Ntzani, No Title. Rockville (MD), (2014) .
- [44] W. Levinson, A. Kao, A. Kuby, R.A. Thisted, Not all patients want to participate in decision making. A national study of public preferences, *J. Gen. Intern. Med.* 20 (June (6)) (2005) 531–535.
- [45] A.K. Skovgaard, C. Fuglsang, E. Mesterton Graae, I. Berg Hougaard, L. Blaabjerg Christoffersen, R. Ljungmann, et al., Sundhedsvæsenet ifølge danskerne [Internet]. Mandag Morgen 72 p. Available from: (2016) . <https://www.mm.dk/artikel/sundhedsvaesenet-ifoelge-danskerne-2>.
- [46] T. Krones, H. Keller, A. Sonnichsen, E.-M. Sadowski, E. Baum, K. Wegscheider, et al., Absolute cardiovascular disease risk and shared decision making in primary care: a randomized controlled trial, *Ann. Fam. Med.* 6 (3) (2008) 218–227.
- [47] A. Luan, K.J. Hui, A.C. Remington, X. Liu, G.K. Lee, Effects of a novel decision aid for breast reconstruction: a randomized prospective trial, *Ann. Plast. Surg.* 76 (Suppl 3) (2016) S249–54 May.
- [48] A. Wilson, S.M. Ronnekleiv-Kelly, T.M. Pawlik, Regret in surgical decision making: a systematic review of patient and physician perspectives, *World J. Surg.* 41 (June (6)) (2017) 1454–1465.
- [49] M. Cuyppers, R.E.D. Lamers, P.J.M. Kil, L.V. van de Poll-Franse, M. de Vries, Longitudinal regret and information satisfaction after deciding on treatment for localized prostate cancer with or without a decision aid. Results at one-year follow-up in the PCPC trial, *Patient Educ. Couns.* (October) (2018).