Patient Education and Counseling xxx (xxxx) xxx–xxx

Contents lists available at ScienceDirect

Patient Education and Counseling

journal homepage: www.elsevier.com/locate/pateducou

The impact of shared decision making on time consumption and clinical decisions. A prospective cohort study

Stine R. Søndergaard[a,b,c,*], Poul H. Madsen[d], Ole Hilberg[c,e], Troels Bechmann[a,c], Erik Jakobsen[a], Karina M. Jensen[b], Karina Olling[b], Karina D. Steffensen[a,b,c]

[a] Department of Oncology, Lillebaelt Hospital, University Hospital of Southern Denmark, Vejle, Denmark
[b] Center for Shared Decision Making, Lillebaelt Hospital, University Hospital of Southern Denmark, Vejle, Denmark
[c] Institute of Regional Health Research, Faculty of Health Sciences, University of Southern Denmark, Odense, Denmark
[d] Department of Internal Medicine, Lillebaelt Hospital, University Hospital of Southern Denmark, Kolding, Denmark
[e] Department of Internal Medicine, The Lung Cancer Diagnostic Organization, Lillebaelt Hospital, University Hospital of Southern Denmark, Vejle, Denmark

ARTICLE INFO

Article history:
Received 12 June 2020
Received in revised form 23 November 2020
Accepted 15 December 2020

Keywords:
Shared decision making
Lung cancer diagnostics
Adjuvant treatment
Breast cancer
Patient decision aid
Decision regret
Consultation length

ABSTRACT

Objective: Concerns of increased time consumption and of the impact on clinical decisions may restrain doctors from shared decision making (SDM). This paper evaluates consultation length and decisions made when using an in-consult patient decision aid (PtDA).
Methods: This prospective cohort study compared an unexposed cohort with a cohort exposed to SDM and a PtDA in two preference-sensitive decision situations: invasive lung cancer diagnostics and adjuvant treatment for early breast cancer. Outcome measures were consultation length and decisions made.
Results: The study included 261 consultations, 115 were in the SDM-exposed cohort. Consultations were inconsiderably longer in the SDM cohort; 2 min, 11 s (p = 0.2217) for lung cancer diagnostics and 3 min, 57 s (p = 0.1128) for adjuvant breast cancer treatment. In lung cancer diagnostics, consultation length became more uniform and decisions tended to become conservative after introduction of SDM. For adjuvant breast cancer, slightly more patients in the SDM cohort chose to decline treatment.
Conclusion: Shared decision making did not take significantly longer time and led to slightly more conservative decisions.
Practice implications: SDM may be implemented without considerable impact on consultation length. The impact on clinical decisions depends mainly on the clinical situation.

1. Introduction

Implementation of shared decision making (SDM) into daily clinical practice may seem inapplicable in the busy and high-responsible work as a doctor. In particular, two concerns may restrain doctors from adopting principles of SDM and using a patient decision aid (PtDA), i.e. the concern of time consumption and of the impact on clinical decisions [1–3].

This study describes time consumption and decisions made before and after introduction of SDM and an in-consult PtDA in two settings: consultations about further investigation based on a small suspicion of lung cancer and consultations about adjuvant treatment after surgery for early stage breast cancer.

Immediate diagnostic work-up to establish whether a patient has lung cancer is typically advised. In some low-risk patients, however, lung cancer seems rather unlikely but cannot be excluded based on the referral note and CT scan of the chest and abdomen. Evidence is lacking as to whether low-risk patients should undergo further invasive diagnostic work-up (with potential risks), be followed with regular CT scans, or need no further evaluation [4–8]. Guidelines encourage the clinician to engage the patient in SDM to discuss preferences in relation to managing a small suspicion of lung cancer [5]. This also seems to be the preference of patients under lung cancer investigation, but implementation of SDM is lacking [9,10].

Preference sensitive decision making is relevant in diagnosis, screening and treatment, although the principles of SDM have probably gained most attention in decisions on treatment. A classic example is whether or not to receive adjuvant treatment after curative surgery for early stage breast cancer. Adjuvant treatment lowers the risk of cancer recurrence, but for many patients the risk is small and adjuvant treatment may cause side effects. Selection of

* Corresponding author at: Lillebaelt Hospital, University Hospital of Southern Denmark, Beriderbakken 4, Vejle, Denmark.
E-mail address: stine.rauff.sondergaard@rsyd.dk (S.R. Søndergaard).

https://doi.org/10.1016/j.pec.2020.12.014
0738-3991/

the right patients for adjuvant treatment continues to be a challenge. Consequently, the choice is a balance between the expected gain and toxicity of the treatment [11–14].

Consultations according to the SDM principles may increase patient engagement in preference sensitive decision making in situations with more than one medically reasonable option. It may also increase clinicians' awareness of patients' different perceptions of the potential benefits or harms of a certain option [15,16].

As earlier reported by our study group, SDM behavior increased significantly in both settings after the introduction of SDM and PtDAs. The highest impact was in the fast-track lung clinic as measured by the option 12 observer tool [17]. Furthermore, as reported elsewhere patient-rated engagement in the decision making process, decisional conflict, and decision regret all improved after the introduction of SDM [18].

PtDAs are tools developed to support the process of SDM. A Cochrane review shows that PtDAs decrease patients' decisional conflict, improve their knowledge of options, and make them more certain about what matters to them [19]. In a subgroup analysis, SDM with cancer patients supported by a PtDA led to decisions more congruent with personal values. [20]. Despite the documented benefits of SDM, its implementation, including PtDAs, into daily clinical practice continues to be a challenge [21,22].

Time constraint is a key barrier towards SDM [21,23]. According to the literature the introduction of SDM has varying effects on the duration of consultations. One systematic review describes 13 randomized clinical trials evaluating consultation length with SDM versus control cohorts [2]. Nine of the trials found no significant difference, three found SDM to increase the consultation length, and in one trial SDM led to shorter consultations. The same review states a lack of evidence on outcomes related to the clinicians' perspective on SDM such as consultation length.

Another key barrier against SDM is the doctor's concern whether the patient will make a preference sensitive treatment choice that the doctor does not perceive as optimal for the patient [1,23]. In the literature, the effect of PtDAs on decisions made varies in different clinical situations. For instance, the use of a PtDA has shown to decrease the number of radical treatment decisions such as elective surgery. [19].

The aim of this paper is to evaluate the impact on consultation length and decisions made when practicing SDM with the use of an in-consult PtDA.

2. Methods

2.1. Design

This prospective cohort study was designed to compare an unexposed control cohort with a cohort exposed to SDM and an in-consult PtDA.

The study took place at the Fast-track Lung Clinic and the Department of Oncology at the same time but independently of each other, both at the public Lillebaelt Hospital, University Hospital of Southern Denmark, Vejle, Denmark. THE STUDY DESIGN IS ILLUSTRATED IN Fig. 1.

The decision situation was the same for patients in the control and SDM cohorts, i.e. diagnostic work-up based on a small suspicion of lung cancer (at the Fast-track Lung Clinic) or adjuvant treatment after breast cancer (at the Department of Oncology). Any doctor involved in a consultation with an included patient participated in the study. Doctors in the SDM cohort had received training in SDM. The study was planned and executed in close cooperation with the hospital's Center for Shared Decision Making.

2.2. Development and use of patient decision aids

The two PtDAs addressing each of the two clinical situations were developed from a generic PtDA template [24,25]. The International Patient Decision Aid Standards (IPDAS) quality criteria guided the systematic process of development and initial

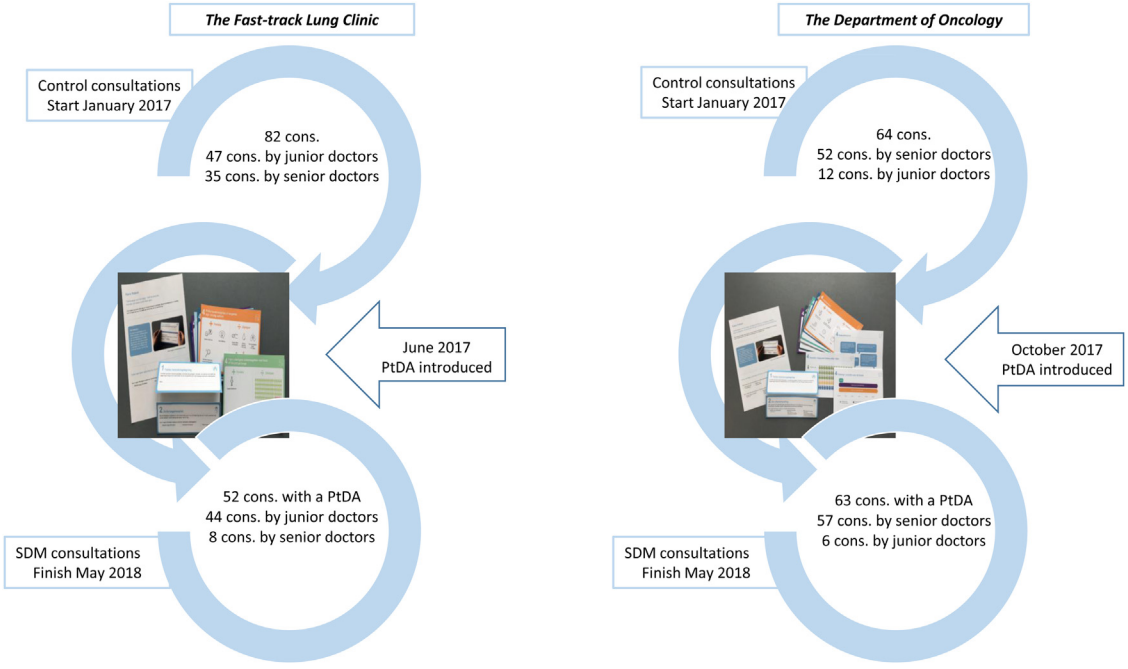

Fig. 1. Study design.
This prospective cohort study was designed to compare an unexposed control cohort with a cohort exposed to SDM and an in-consult PtDA.
During the control phase 146 (64 breast, 82 lung) consultations took place from january 2017 to september 2017.
The SDM phase ran from june 2017 to may 2018 with 115 (63 breast, 52 lung) consultations.
Introduction of the PtDA included an 8 -h training session with a main focus on SDM, secondarily on the PtDA.
Abbreviations: PtDA: Patient Decision Aid. SDM: Shared Decision Making. Cons: Consultations.

testing [24,26,27]. The design supports a four step approach to SDM: choice talk, preference talk, option talk, and decision talk. Further details are available elsewhere [18,26].

The PtDAs were introduced to the staff after the control phase and prior to the SDM phase. The main focus was SDM and secondarily the PtDA. The introduction was an 8 -h training session with 8–10 doctors and nurses in each setting. Staff employed after the introduction was trained one-on-one by the study nurse for half an hour.

To prepare for the consultation, patients in the SDM cohort were given a sheet with brief information about SDM and a few questions related to patient preferences. The PtDA was used by the doctor during the consultation to support the practice of SDM and given to the patient after the consultation.

2.3. Diagnostic work-up based on a small suspicion of lung cancer

Annually, 1600 patients are referred to the Fast-track Lung Clinic on suspicion of lung cancer, and malignancy is confirmed in around 450. The enrolled patients had low risk of lung cancer. The majority had passed hemoptysis and undergone subsequent chest and abdomen CT scan with no apparent malignancy (risk of malignancy < 2 %) [28,29]. Others had one or two pulmonary nodules of 8–10 mm (risk of malignancy ≤ 5 %) [8] or a mediastinal/hilar lymphadenopathy of 1–2 cm (risk of malignancy < 5 %) [7]. Any increased clinical suspicion of malignancy or other condition requiring treatment excluded the patient from the study. The options were invasive evaluation (bronchoscopy or biopsy), follow-up with CT scans, or end of diagnostic work-up in the Fast-track Lung Clinic. Included patients consulted either a junior (not yet a fully trained specialist) or a senior (a medical specialist) doctor. For further details, please refer to our earlier work [18].

2.4. Adjuvant treatment after breast cancer

Around 500 women are annually offered adjuvant treatment after early breast cancer at the Department of Oncology. Most of these women consult one of four senior doctors. After surgery for early breast cancer, adjuvant treatment involves chemotherapy, HER2-targeted treatment, endocrine treatment, zoledronic acid treatment, and/or adjuvant radiotherapy, which may all cause side effects, e.g. neutropenic fever, alopecia, cardiac complications, peripheral neuropathy. The reduction in risk of recurrence varies substantially from patient to patient depending on tumor and patient characteristics. The inclusion criteria were age above 18 years and clinical indication for medical adjuvant treatment according to national guidelines. Exclusion criteria were suspicion of disseminated cancer, neoadjuvant treatment, and inability to understand the information given on the study or planned treatment.

2.5. Collection of data

In both settings, consultation length was measured by a study nurse who also entered the decision made in the study database. Time registration began when the doctor and the patient were both present in the consultation room and ended when the patient left the room. The study nurse was not in the consultation room. The number and duration of follow-up nurse consultations were registered by the study nurse.

All patients gave written and orally informed consent to participating in the study. In accordance with Danish law, this non-biological study did not require submission for review by the Health Research Ethics Committee. Data handling and processing was approved by the Danish Data Protection Agency.

Table 1
Baseline patient characteristics. The SDM and control cohorts in the two settings. SDM = Shared Decision Making. ER = Estrogen status, positive when > 10 %.

Breast cancer patients				Patients with low risk of lung cancer		
	Control n = 64	SDM n = 63	*p*	Control n = 82	SDM n = 52	*p*
Age, mean (SD)	59 (11)	61 (11)	*0.233*	55 (15)	58 (16)	*0.262*
Gender (%)			*0.000*			*0.978*
Male	0 (0)	0 (0)		55 (67)	34 (65)	
Female	64 (100)	63 (100)		27 (33)	18 (35)	
Education level (%)			*0.792*			*0.942*
Public School	14 (22)	8 (13)		19 (23)	15 (29)	
High School	2 (3)	0 (0)		3 (4)	0 (0)	
Skilled worker	10 (16)	22 (35)		20 (24)	14 (27)	
Lower sec. education	14 (22)	13 (21)		13 (16)	5 (10)	
Upper sec. education	19 (30)	16 (25)		19 (23)	11 (21)	
Academic education	4 (6)	3 (5)		7 (9)	4 (8)	
Other	1 (1)	1 (1)		1 (1)	3 (6)	
Marital status (%)			*0.543*			*0.098*
Married/cohabitant	48 (75)	51 (81)		61 (74)	31 (60)	
Single	13 (20)	9 (14)		16 (20)	16 (31)	
Divorced	3 (5)	3 (5)		5 (6)	5 (10)	
Work (%)			*0.653*			*0.497*
Full time	20 (31)	17 (27)		38 (46)	21 (40)	
Part time	8 (13)	8 (13)		6 (7)	3 (6)	
Retired	27 (42)	30 (48)		33 (40)	24 (46)	
Absent	9 (14)	7 (11)		1 (1)	2 (4)	
Unemployed	0 (0)	1 (1)		4 (5)	2 (4)	
Tumor characteristics				Reason for referral		
TN status				*Hemoptysis*		
	51 (80)	39 (62)	*0.027*	63 (77)	50 (96)	*0.003*
T2	13 (20)	20 (32)	*0.142*	*Nodulus*		
T3	0 (0)	4 (6)	*0.041*	7 (9)	2 (4)	*0.290*
N positive	16 (25)	20 (32)	*0.399*	*Lymphadenopathy*		
ER positive	62 (97)	55(87)	*0.045*	12 (15)	0 (0)	*0.004*
HER2 overexpression	14 (22)	6 (10)	*0.056*			

In order to investigate the possible correlation between consultation time and observed level of SDM we were given access to the earlier mentioned OPTION 12 data by its authors [17]. OPTION 12 is measured on a scale from 0 to 48 with higher scores indicating more SDM. The data included OPTION 12 results from 23 consultations at the Fast-track Lung Clinic and 31 consultations at the Department of Oncology.

2.6. Decision regret scale

Six months after the consultation, the validated 5-item Decision Regret Scale (DRS) questionnaire was sent to the patients. It measures regret after healthcare decisions on a scale from 0 to 100; the higher the score, the more regret [30,31]. The present study analyzed data from the DRS of the breast cancer patients whereas data of the lung cancer patients were reported previously [18].

2.7. Statistical analysis

The STATA/IC 16. 0 software (StataCorp LLC, College Station, TX, USA) was used for statistical analysis. Means with standard deviation (SD) and comparisons between the cohorts with t-tests were used for continuous measures. For the control cohort in the Fast-track Lung Clinic the data on consultation length were only nearly normally distributed since some (few) consultations were either very short or very long. However, since there were more than 50 patients in the cohort, we assumed the *t*-test was valid. The other three cohorts (SDM cohort in the Fast Track Lung Clinic, control and SDM cohorts at the Department of Oncology) were normally distributed. Fisher's exact-test was used for categorical measures. P-values are two-sided. Linear regressions of patient characteristics were performed separately for the lung cancer evaluation cohort and adjuvant breast cancer cohort in order to detect potential clinical differences between the control and SDM cohorts. Linear regressions of consultation time versus OPTION 12 score were performed. **A** subgroup analysis was performed to elucidate any difference in the impact on consultation length and decision made between junior and senior doctors.

3. Results

3.1. Patients

A total of 261 patients participated in this cohort study (Fig. 1). Apart from tumor characteristics and reason for referral there was no significant difference in patient characteristics between the related SDM and control cohorts (Table 1).

3.2. Consultation length: diagnostic work-up on a small suspicion of lung cancer

The mean consultation length did not differ significantly between the control cohort (22 min, 5 s) and the SDM cohort (24 min, 16 s), p = 0.2217, difference =2 min, 11 s (95 % CI: −1 min, 20 s–5 min, 43 s). However, in the control cohort consultation length ranged from 3 min, 23 s to 63 min, 44 s. The shortest consultation in the SDM cohort was 7 min, 2 s and the longest 38 min, 20 s. In other words, SDM led to more uniform consultation lengths illustrated by a significant difference in the mean standard deviation, i.e. 13 min, 13 s in the control cohort and 7 min, 23 s in the SDM cohort ($p < 0.001$). Please refer to Fig. 2.

In the control cohort 47 of 82 (57 %) patients consulted a junior doctor; this was the case for 44 of 52 (84 %) patients in the SDM cohort. For junior doctors, the mean consultation length in the SDM cohort (25 min, 25 s) was slightly shorter than in the control cohort (27 min, 2 s), but the difference of 1 min, 37 s was not significant (p = 0.4798, 95 % CI: - 2 min, 55 s – 6 min, 9 s). Conversely, the consultation length for senior doctors was on average 2 min, 31 s longer using SDM, also not significant (15 min, 25 s in the control cohort and 17 min, 56 s in the SDM cohort, p = 0.4785, 95 % CI: – 9 min, 37 s – 4 min, 35 s).

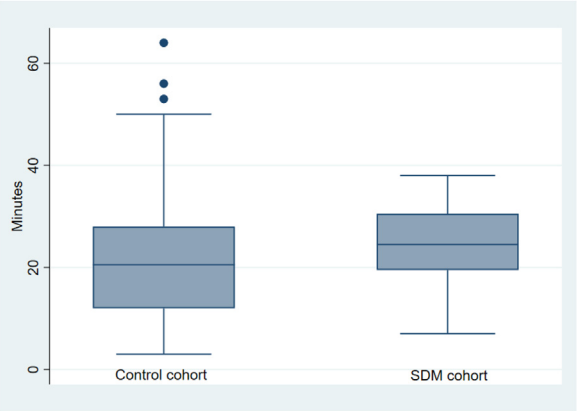

Fig. 2. Consultation length for diagnostic work-up based on a small suspicion of lung cancer in the control cohort (n = 82) and the SDM cohort (n = 52).

A sub-group of patients consulted with a nurse after the doctor's consultation. This follow-up consultation most often focused on practical planning of further diagnostic work-up. The number of patients consulting with a nurse did not change significantly by the introduction of SDM (44 % and 40 % in the control and SDM cohorts, respectively, p = 0.688), neither did the mean consultation length of the nurses' consultations (p = 0.3519).

Twenty-three consultations (13 controls, 10 SDM) were scored according to the OPTION 12 observer tool. With a regression coefficient of 7 s (95 % CI -11.1 sec–25.2 sec) no significant correlation was found between OPTION 12 score and consultation length (supplementary Fig. 1).

3.3. Consultation length: adjuvant treatment after breast cancer

Mean consultation length differed significantly between the control and SDM cohorts (34 min, 40 s versus 39 min, 58 s, difference **=** 5 min, 17 s, p = 0.0227, 95 % CI: 45 s – 9 min, 50 s). However, 14 of the 63 patients in the SDM cohort were also informed about a new prospective follow-up biomarker study, which increased the mean consultation time disproportionally to 44 min, 21 s. For the remaining 49 patients in the SDM cohort the mean consultation time was 38 min, 37 s. Consultation length did not differ significantly between the control cohort and these 49 SDM patients (3 min, 57 s longer for the 49 SDM patients, p = 0.1128, 95 % ci: −57 s – 8 min, 50 s). Fig. 3 illustrates the consultation length of the control cohort and the 49 patients of the SDM cohort. The mean standard deviation for consultation time did not differ significantly between the two cohorts (p = 0.9742), thus variance in consultation length was similar across cohorts.

Four senior doctors saw 109 of the 127 patients. For the individual doctor, SDM led to an increased mean consultation length (range 2 min, 59 s to 10 min, 38 s), neither of which was significant (p = 0.3850, p = 0.1198, p = 0.1340, p = 0.1780).

For the remaining 18 consultations (12 control; 6 SDM) by different junior doctors there was a significant increase of 8 min, 58 s in the mean consultation length (p = 0.0389, 95 % CI: 31 s – 17 min, 26 s). After the consultation with the doctor, all patients had a consultation with a nurse. The mean length of the nurses' consultations in this setting did not differ significantly as a result of SDM (p = 0.3519).

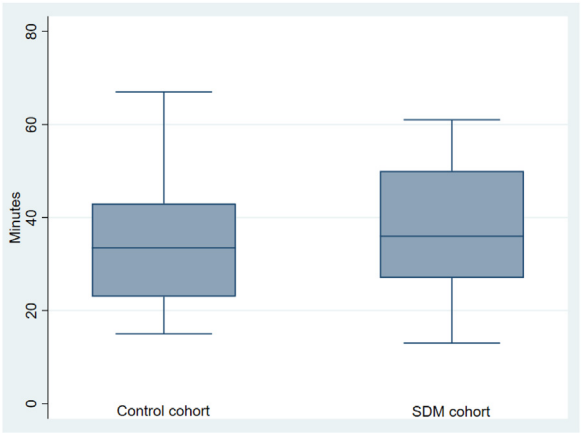

Fig. 3. Consultation length for adjuvant treatment after breast cancer in the control cohort (n = 64) and the SDM cohort (n = 49).

Thirty-one consultations (16 controls, 15 SDM) were scored according to the OPTION 12 observer tool. With a regression coefficient of 21 s (95 % CI −16 s - 59 s, p = 0.258) no correlation was found between OPTION 12 score and consultation length (supplementary Fig. 2).

3.4. Decision made: diagnostic work-up on a small suspicion of lung cancer

As illustrated in Tables 2a and 2b, SDM led to a trend towards fewer decisions on invasive diagnostic work-up in favor of either ending the patient's course in the Fast-track Lung Clinic or follow-up with CT scans (p = 0.098). Due to practical circumstances, most of the doctors in the SDM cohort were junior; 44 out of 52 consultations were conducted by junior doctors in the SDM cohort. Interestingly, in consultations by junior doctors SDM led to significantly fewer decisions on further diagnostic work-up for lung cancer (p = 0.009).

3.5. Decision made: adjuvant treatment after breast cancer

Table 3 displays the distribution of decisions on adjuvant treatment after breast cancer. In both cohorts, most patients received adjuvant treatment, but it was slightly more frequently declined in the SDM cohort (p = 0.047).

Table 4 illustrates treatment recommendations, decisions made during and after the consultation, and initiation of treatments in the two breast cancer cohorts. Endocrine treatment was recommended and initiated in most patients. After one year, five patients in each cohort had stopped the endocrine treatment.

Data from the DRS questionnaire six months after the consultation were obtained from the majority of the breast cancer patients. On a scale from 0 (no regret) to 100 the mean DRS score was 25.55 in the control cohort (63 respondents) and 20.59 in the SDM cohort (59 respondents), (p = 0.1172). Inspired by others, DRS responses were divided into two groups; no or mild regret (DRS scores 0–25) and moderate to strong regret (DRS scores > 25) [32]. Thirty-two (51 %) patients in the control cohort and 40 patients (68 %) in the SDM cohort had no or mild regret (p = 0.067). Table 5 shows decisions and DRS scores for patients declining treatment at the Department of Oncology.

Table 2a
Decision made: Diagnostic work-up based on a small suspicion of lung cancer.

Decision	Control cohort, n (%)	SDM cohort, n (%)
Further diagnostic evaluation	36 (44)	15 (29)
No further diagnostic evaluation	33 (40)	31 (60)
Follow-up	13 (16)	6 (11)
Total	82 (100)	52 (100)

Follow-up: a CT scan three or six months after the consultation.
p = 0.098.

Table 2b
Decision made: Diagnostic work-up based on a small suspicion of lung cancer, junior doctor.

Decision	Control cohort, n (%)	SDM cohort, n (%)
Further diagnostic evaluation	24 (51)	11 (25)
No further diagnostic evaluation	15 (32)	28 (64)
Follow-up	8 (17)	5 (11)
Total	47 (100)	44 (100)

Follow-up: a CT scan three or six months later.
p = 0.009.

Table 3
Decision made: Adjuvant treatment after breast cancer.

Decision	Control cohort, n (%)	SDM cohort, n (%)
Adjuvant treatment	63 (98)	56 (89)
Part of the adjuvant treatment	1 (2)	5 (8)
No adjuvant treatment	0 (0)	2 (3)
Total	64 (100)	63 (100)

p = 0.047.

4. Discussion and conclusion

4.1. Discussion

SDM cannot be successfully implemented without the goodwill of the clinicians. Neither the political call for increased patient engagement nor longstanding evidence in favor of SDM seems to be enough to ensure commitment [19,33,34]. Busy and conscientious clinicians have reasonable considerations as to time consumption and influence on patient treatment.

4.2. Impact on consultation length

The fact that the doctors involved in the study were all at the beginning of their learning curve with SDM did not result in significantly longer consultations, neither in the Fast-track Lung Clinic nor at the Department of Oncology. This could lead to concerns as to whether SDM during the doctor's consultation would increase the length of the nurse's consultation. Fortunately, such inter-professional move of time burden did not occur. Our results indicate that consultations based on SDM are likely to last a few minutes longer. For the healthcare system, such minor increments of consultation time – at least for beginners in SDM - may be a reasonable price for increased patient engagement and derived benefits such as increased compliance and possible savings in healthcare [19,35,36]. As earlier described our intervention led to significantly higher levels of observed SDM behavior and patients reported significantly higher levels of engagement [17,18]. Thus, SDM may take up to a few minutes longer, but it is unlikely to ruin the planned schedule – even for beginners in the discipline of SDM.

In the diagnostic setting of the Fast-track Lung Clinic, the length of consultations went from varying tremendously to being more uniform after the introduction of SDM - an unexpected and positive outcome. An observation made during the study may explain this phenomenon. In the SDM cohort, the investigators observed that the junior doctors rarely left the consultation room to ask a senior doctor for advice. This was more often the case in the

Table 4
Treatment recommendation, decision and initiation: Adjuvant treatment after breast cancer. Recommendations were based on tumor characteristics and national guidelines.

Control cohort (n = 64)	Prior to consultation	Decision at consultation			Treatment initiation	
Treatments	Recommendation	Treatment	Time to reflect	No treatment	Treatment initiation	No treatment
Chemotherapy	34	32	2	0	33	1
HER2 targeted	5	5	0	0	5	0
Radiotherapy	55	53	2	0	55	0
Endocrine	62	60	2	0	61	1
Zol. acid	45	43	2	0	45	0
SDM cohort (n = 63)	Prior to consultation	Decision at consultation			Treatment initiation	
Treatments	Recommendation	Treatment	Time to reflect	No treatment	Treatment initiation	No treatment
Chemotherapy	36	28	4	4	29	7
HER2 targeted	7	6	0	1	6	1
Radiotherapy	56	52	4	0	54	2
Endocrine	55	53	2	0	53	2
Zol. acid	51	49	2	0	48	3

Table 5
Patients at the Department of Oncology declining treatment. Patient D was premenopausal. Patients E and F declined chemotherapy due to comorbidity. Patient F did not return the DRS questionnaire. Patient G had decided prior to the consultation not to receive adjuvant treatment. Abbreviations: SDM: Shared Decision Making, DRS: Decision Regret Score.

Patient	Cohort	Recommendation	Treatment initiation	Decision Regret Score
A	Control	1, 2, 3, 4	2, 4	0
B	SDM	1, 2, 3, 4	2, 3, 4	0
C	SDM	1, 2, 3, 4	2, 3, 4	5
D	SDM	1, 2, 3	2, 3	45
E	SDM	1, 3, 4	3, 4	0
F	SDM	1, 2, 4	4	–
G	SDM	1, 2, 3, 4	None	0
H	SDM	1, 3, 4	None	15

Definitions: 1 = Chemotherapy, 2 = Radiotherapy, 3 = Endocrine therapy, 4 = Zoledronic acid.

control cohort and consequently, the junior doctor would spend time waiting for an available senior doctor.

Junior doctors had substantially longer consultations than senior doctors. Interestingly, in most cases SDM led to trends towards slightly shorter consultations for junior doctors and slightly longer consultations for senior doctors. It can be speculated that SDM helped the patients to more time to reflect and talk in the consultations with the senior doctors – and perhaps the junior doctors were more structured and clinically confident in the decision process as a result of SDM.

In the literature, three randomized trials found improved patient-rated outcomes without increase of consultation time when using SDM and an in-consult PtDA [37–39]. Whelan et al. investigated decision making in relation to adjuvant chemotherapy after surgery for node negative breast cancer in 176 patients. They found patients to be more knowledgeable and satisfied in the PtDA cohort with no increment of consultation time compared to the control cohort [38]. Two systematic reviews confirm the assumption that SDM supported by a PtDA does not automatically lead to longer consultation time [2,19].

It takes time to build new habits. In the case of SDM supported by an in-consult PtDA, our results and knowledge so far may reduce the concern of clinicians as to major time consumption.

4.2.1. The impact on the decision made

Doctors often witness advanced disease, including advanced breast or lung cancer. Therefore, presenting options of declining diagnostic work-up or treatment that could prevent advanced disease may seem irresponsible. This issue is the second key barrier discussed here, i.e. the understandable concern among doctors as to the impact of SDM on clinical decisions.

In diagnostic work-up on a small suspicion of lung cancer significantly fewer patients consulted by a junior doctor underwent invasive diagnostic evaluation. Since these patients reported significantly lower decision regret [18], declining further diagnostic evaluation may have been in line with their own preferences. In adjuvant treatment after breast cancer only few more patients declined adjuvant treatment after the introduction of SDM. DRS scores tended to be lower in the SDM cohort and in all but one case they were very low among those declining treatment. Most breast cancer patients received adjuvant treatment as recommended. The level of impact on the clinical decisions therefore seems to depend more on the clinical situation than the mere concept of SDM.

Our findings are in line with the literature [19]. A randomized study with 204 patients at low risk of acute coronary syndrome compared the use of an in-consult PtDA with usual care in the decision on whether or not to undergo a cardiac stress test with potential side effects [40]. In their study SDM led to increment of patient engagement as measured by the OPTION instrument, greater knowledge and less cardiac stress testing. Thus, in some clinical situations SDM may provide knowledge to patients and empower them to decline unnecessary treatment or evaluations. This is in line with our study. Prior to the present study, the decision on invasive diagnostic evaluation on a small suspicion of lung cancer was mainly based on the senior doctor's preferences. SDM made it clear to the patient and the doctor (often junior) that the next step was not necessarily given but represented a subject for active decision-making between them. It is likely that SDM led to decisions based on the patient's preferences instead of those of the senior doctor, a central step towards patient-centered care.

Conservative decisions on treatment or diagnostic work-up are not negative aspects of SDM. “Choosing Wisely” campaigns have

emerged in recent years acknowledging the potential harms of overtreatment [41]. In our opinion and in light of the "Choosing Wisely" campaigns, conservative decisions of foregoing options are not bad decisions when in line with patient preferences.

This study has several limitations. Most importantly, a randomized design would have strengthened it. Also, a larger study, with more patients, doctors and settings, would have strengthened our results and made them more applicable in general healthcare. Since the investigators were not present in the consultation room, the amount of time spent on SDM is not known. Tumor characteristics and reason for referral were different in the related SDM and control cohorts. Breast cancer tumors were bigger and hemoptysis was the main reason for referral on small suspicion of lung cancer in the SDM cohort**s**. Due to practicalities, the distribution of junior and senior doctors in the two cohorts in the Fast-track Lung Clinic was not even. Other limitations, mainly concerning the practicalities and design of the study, have been described previously [18]. The limitations should be taken into consideration in the interpretation of our results.

4.3. Conclusion

The introduction of SDM and an in-consult PtDA in two different clinical settings did not increase the consultation length significantly. Shared decision making led to more conservative-decisions, although the degree of the impact depended on the clinical situation.

4.4. Practical implications

Following this prospective cohort study, SDM and the PtDAs have been implemented into daily clinical practice at both the Fast-track Lung Clinic and the Department of Oncology without causing notably longer consultations or inappropriate decision making.

Funding

Financial support for this study was provided by the Danish Health Authority (grant number 1-1010-116/7) and Lillebaelt Hospital, Vejle, a public, tax-financed hospital. The funding agreement ensured the authors' independence in designing the study, interpreting the data, writing and publishing the report.

CRediT authorship contribution statement

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

Declaration of Competing Interest

The authors declare that there is no conflict of interest.

Acknowledgements

The authors wish to thank the Design School Kolding for their great contribution to the development of the PtDAs, Karin Larsen for linguistic editing of the manuscript, and the staff at the Fast-track Lung Clinic, the Department of Oncology, and the Center for Shared Decision Making, Lillebaelt Hospital, University Hospital of Southern Denmark, Vejle, Denmark.

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.2020.12.014.

References

[1] F. Légaré, P. Thompson-Leduc, Twelve myths about shared decision making, Patient Educ. Couns. 96 (3) (2014) 281–286.
[2] C.C. Dobler, M. Sanchez, M.R. Gionfriddo, N.A. Alvarez-Villalobos, N. Singh Ospina, G. Spencer-Bonilla, et al., Impact of decision aids used during clinical encounters on clinician outcomes and consultation length: a systematic review, BMJ Qual. Saf. 28 (6) (2019) 499–510.
[3] A. Lloyd, N. Joseph-Williams, A. Edwards, A. Rix, G. Elwyn, Patchy "coherence": using normalization process theory to evaluate a multi-faceted shared decision making implementation program (MAGIC), Implement. Sci. 8 (1) (2013) 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] M.K. Gould, J. Donington, W.R. Lynch, P.J. Mazzone, D.E. Midthun, D.P. Naidich, et al., Evaluation of individuals with pulmonary nodules: when is it lung cancer? Diagnosis and management of lung cancer 3rd ed: American college of chest physicians evidence-based clinical practice guidelines, Chest 143 (5 SUPPL) (2013) 93–120.
[6] B. Hirshberg, 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 (September (10)) (2013) 910–919.
[9] A.T. Brenner, T.L. Malo, M. Margolis, J. Elston Lafata, S. James, M.B. Vu, et al., Evaluating shared decision making for lung cancer screening, JAMA Intern. Med. 178 (10) (2018) 1311–1316.
[10] Marc R. Freiman, Jack A. Clark, Christopher G. Slatore, Steven Woloshin, Lisa M. Schwartz, Soylemez Wiener, Patients' knowledge, beliefs, and distress associated with detection and evaluation of incidental pulmonary nodules for cancer: results from a multi-center survey, J. Thorac. Oncol. 11 (5) (2017) 700–708.
[11] Y.M. Kirova, S. Carroll, A. Fourquet, B. Offersen, C. Aristei, J.-Y. Chen, The St Gallen international expert consensus on the primary therapy of early breast cancer 2017: the point of view of an international panel of experts in radiation oncology, Ann. Oncol. Off. J. Eur. Soc. Med. Oncol. 29 (January (1)) (2018) 280–281.
[12] C. Taylor, F.K. Duane, D. Dodwell, R. Gray, Z. Wang, Y. Wang, et al., Estimating the Risks of Breast cancer radiotherapy: evidence from modern radiation doses to the lungs and Heart and from previous randomized trials, J. Clin. Oncol. 35 (15) (2017) 1641–1649.
[13] I.H. Kunkler, L.J. Williams, W.J.L. Jack, D.A. Cameron, J.M. Dixon, Breast-conserving surgery with or without irradiation in women aged 65 years or older with early breast cancer (PRIME II): a randomised controlled trial, Lancet Oncol [Internet] 16 (3) (2015) 266–273, doi:http://dx.doi.org/10.1016/S1470-2045(14)71221-5 Available from:.
[14] K. Albain, S. Anderson, R. Arriagada, W. Barlow, J. Bergh, J. Bliss, et al., Comparisons between different polychemotherapy regimens for early breast cancer: meta-analyses of long-term outcome among 100 000 women in 123 randomised trials, Lancet [Internet] 379 (9814) (2012) 432–444, doi:http://dx.doi.org/10.1016/S0140-6736(11)61625-5 Available from:.
[15] A. Coulter, Patient engagement-what works? J. Ambul. Care Manage. 35 (2) (2012) 80–89.
[16] 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.
[17] K. Olling, M. Stie, B. Winther, K.D. Steffensen, The impact of a patient decision aid on shared decision-making behaviour in oncology care and pulmonary medicine-A field study based on real-life observations, J. Eval. Clin. Pract. (May) (2019), doi:http://dx.doi.org/10.1111/jep.13196.
[18] Sr Sondergaard, Ph Madsen, O. Hilberg, Km Jensen, K. Olling, Kd. Steffensen, A prospective cohort study of shared decision making in lung cancer diagnostics: impact of using a patient decision aid, Patient Educ. Couns. (May) (2019), doi:http://dx.doi.org/10.1016/j.pec.2019.05.018.
[19] D. Stacey, F. Legare, K. Lewis, M.J. Barry, C.L. Bennett, K.B. Eden, et al., Decision aids for people facing health treatment or screening decisions, Cochrane database Syst Rev [Internet] (2017), doi:http://dx.doi.org/10.1002/14651858.CD001431.pub5 Apr 12 [cited 2020 Mar 6];4(4):CD001431. Available from:.
[20] K. McAlpine, Kb Lewis, Lj Trevena, D. Stacey, What is the effectiveness of patient decision aids for cancer-related decisions? A systematic review subanalysis, JCO Clin. Cancer Informatics (2) (2018) 1–13.
[21] F. Légaré, S. Ratté, K. Gravel, I.D. Graham, Barriers and facilitators to implementing shared decision-making in clinical practice: update of a systematic review of health professionals' perceptions, Patient Educ. Couns. 73 (3) (2008) 526–535.

[22] 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 Gesundhwes (Jun) (2017) 36–40 123–124.
[23] 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.
[24] K. Steffensen, K. Dankl, Shared decision making: empathic encounters between design and healthcare, in: P. Desmet, S. Fokkinga, G. Ludden, N. Cila, H. van Zuthem (Eds.), Proceedings of the 10th International Conference on Design & Emotion: Celebration & Contemplation, Des Emot Soc, 2016, pp. 80–89 Sep 1.
[25] C. Akoglu, K. Dahl Steffensen, K. Dankl, Design and healthcare collaboration: developing a generic patient decision aid in a Danish hospital context, 21st DMI Acad Des Manag Conf Proc Next Wave, Des Manag Inst., 2018 1350-20181360 DMI.
[26] 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 Heal. Vol 7 (Issue 1) (2019).
[27] A. Coulter, D. Stilwell, J. Kryworuchko, Pd Mullen, Cj Ng, T. Van Der Weijden, A systematic development process for patient decision aids, BMC Med. Inform. Decis. Mak. [Internet] 13 (SUPPL. 2) (2013) S2. Available from: http://www.biomedcentral.com/1472-6947/13/S2/S2.
[28] S. Bønløkke, L.M. Guldbrandt, T.R. Rasmussen, Bronchoscopy in patients with haemoptysis and normal computed tomography of the chest is unlikely to result in significant findings, Dan. Med. J. 62 (8) (2015).
[29] G. McGuinness, J.R. Beacher, T.J. Harkin, S.M. Garay, W.N. Rom, D.P. Naidich, Hemoptysis: prospective high-resolution CT/bronchoscopic correlation, Chest 105 (April (4)) (1994) 1155–1162.
[30] 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. Mak. 36 (August (6)) (2016) 777–790.
[31] 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. Mak. 23 (4) (2003) 281–292.
[32] 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. [Internet] 17 (1) (2016) 1–11, doi:http://dx.doi.org/10.1186/s12875-016-0558-0 Available from:.
[33] Danish Health Authority, Cancer Action Plan [Internet] [cited 2020 Oct 6]. Available from:, (2016) . https://www.sst.dk/da/viden/kraeft/kraeftplaner/kraeftplan-iv.
[34] Am Stiggelbout, Ah Pieterse, J.C.J.M. De Haes, Shared decision making: concepts, evidence, and practice, Patient Educ. Couns. [Internet] 98 (10) (2015) 1172–1179, doi:http://dx.doi.org/10.1016/j.pec.2015.06.022 Available from:.
[35] F. Légaré, H.O. Witteman, Shared decision making: examining key elements and barriers to adoption into routine clinical practice, Health Aff. 32 (2) (2013) 276–284.
[36] M.A. Emily Oshima Lee, Ezekiel J. Emanuel, Shared decision making to improve care and reduce costs, N. Engl. J. Med. 368 (1) (2013) 4–6.
[37] A. Loh, D. Simon, Ce Wills, L. Kriston, W. Niebling, M. Härter, The effects of a shared decision-making intervention in primary care of depression: a cluster-randomized controlled trial, Patient Educ. Couns. 67 (3 SPEC. ISS) (2007) 324–332.
[38] T. Whelan, C. Sawka, M. Levine, A. Gafni, L. Reyno, A. Willan, et al., Helping patients make informed choices: a randomized trial of a decision aid for adjuvant chemotherapy in lymph node-negative breast cancer, J. Natl. Cancer Inst. 95 (8) (2003) 581–587.
[39] A. LeBlanc, A.T. Wang, K. Wyatt, M.E. Branda, N.D. Shah, H. Van Houten, et al., Encounter decision aid vs. clinical decision support or usual care to support patient-centered treatment decisions in osteoporosis: the osteoporosis choice randomized trial II, PLoS One [Internet] 10 (May (5)) (2015) e0128063, doi: http://dx.doi.org/10.1371/journal.pone.0128063 Available from:.
[40] E.P. Hess, M.A. Knoedler, N.D. Shah, J.A. Kline, M. Breslin, M.E. Branda, et al., The chest pain choice decision aid: a randomized trial, Circ. Cardiovasc. Qual. Outcomes 5 (3) (2012) 251–259.
[41] O. Kherad, N. Peiffer-Smadja, L. Karlafti, M. Lember, Aerde N. Van, O. Gunnarsson, et al., The challenge of implementing less is more medicine: a European perspective, Eur. J. Intern. Med. (April) (2020).