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Shared decision making in recurrent ovarian cancer: Implementation of patient decision aids across three departments of oncology in Denmark

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ABSTRACT

Objective: Patients with relapsed ovarian cancer are offered multiple treatment options. To match treatment with the individual patient's life situation and preferences, healthcare professionals can apply shared decision making (SDM) including patient decision aids (PtDAs).
This study aimed to evaluate the implementation of two different PtDAs in consultations with patients suffering from relapsed ovarian cancer.
Methods: We analyzed the following data before and after implementation of the PtDAs: 1) observed SDM using the OPTION instrument, 2) physician treatment recommendations, and 3) patients' and physicians' evaluations of SDM in consultations using the CollaboRATE, SDM-Q-9, and SDM-Q-Doc.
Results: Significant improvement in observed SDM was found after the implementation ($p = 0.002$). Improvement of SDM was detected in consultations conducted by physicians reporting more than two hours of SDM-training ($p < 0.001$), but not when physicians reported less than two hours of SDM-training.
No before/after differences in treatment recommendations and in patients' and physicians' evaluations were found.
Conclusion: Implementation of PtDAs improved the level of observed SDM. Training of physicians in SDM is necessary for improved SDM practice.
Innovation: Discussing oncological treatment options with the use of PtDAs is not standard practice in Denmark. The present study is one of the first Danish studies focusing on how to implement SDM and PtDAs in oncological consultations.

HIGHLIGHTS

- Patient decision aids (PtDAs) might improve shared decision making in consultations.
- Two different PtDAs were implemented, one for platinum-sensitive and one for platinum-resistant relapse of ovarian cancer.
- Observed level of shared decision making improved after implementation.
- More than two hours of physician SDM skills training was necessary for improvement.

Abbreviations: CSDM, Center for Shared Decision Making, Vejle Hospital, Denmark; CT, Computed Tomography; PtDA, Patient Decision Aid; RCT, Randomized Controlled Trial; SDM, Shared Decision Making.

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1. Introduction

Ovarian cancer is the term commonly used for a cancer arising in the ovary, fallopian tube or peritoneum. Most ovarian cancer patients are diagnosed at advanced stage with intraabdominal dissemination or metastatic disease and the risk of relapse is very high. At time of relapse, the time interval from the last dose of platinum-containing chemotherapy to the diagnosis of relapse is used to categorize the relapse as either platinum-sensitive or platinum-resistant. The length of this time interval has a huge impact on the treatment options and prognosis. Treatment options include debulking surgery, various types of single agent and combination chemotherapy, biologically targeted treatment and watchful waiting [1].

Shared decision making (SDM) is "an approach where clinicians and patients make decisions together using the best available evidence. Patients are encouraged to think about the available screening, treatment, or management options and the likely benefits and harms of each so that they can communicate their preferences and help to select the best course of action for them." [2].

The goal of SDM is for the patients to receive the best treatment based on their life circumstances and preferences. SDM has been shown to improve cognitive-affective outcomes such as patient satisfaction, patient knowledge, confidence with the decision, trust in physician, and anxiety. The effects on behavioral and health outcomes are less studied [3]. Several models of SDM have been proposed. Elwyn et al. suggest that the patient-provider consultation follows a multi-stage process described as the "three-talk model" with a team talk, an option talk and a decision talk [4]. The model can be used in the training of healthcare professionals for acquisition of SDM skills.

Patient decision aids (PtDAs) are support tools applicable for counseling and shared decision making in clinical encounters. Typically, PtDAs are pamphlets, videos, or web-based tools describing important elements of the treatment decision [5]. A PtDA provides the patient and the healthcare professional with a common basis for discussing pros and cons of specific treatment options. They support the patients to choose treatment and care in accordance with their values and preferences. A Cochrane review on the effects of PtDAs applied in clinical encounters concluded that the use of PtDAs made patients feel more knowledgeable and accurate in risk perceptions and offered them a more active role in the decision making process [6]. Clinical practice guidelines and international organizations recommend the use of PtDAs as a strategy to improve healthcare but also to reduce overtreatment. In 2016, the Danish Health Authorities launched "Cancer Plan IV" with a strong focus on SDM and PtDAs initiatives [7].

Clarification of the patient's life circumstances and preferences in the discussion of treatment options may influence the decision on treatment [8]. Incorporating SDM and PtDAs in consultations with ovarian cancer patients appears promising, but evidence of effectiveness and the optimal implementation of SDM is limited [9-12]. This study aimed to develop, implement, and analyze the effects of two PtDAs implemented in decision making consultations with patients suffering from platinum-sensitive or platinum-resistant relapse of ovarian cancer at three Danish departments of oncology.

Based on the goals of SDM and PtDAs we hypothesized that observed ratings (by observers in the consultation room) as well as perceived ratings of SDM (by patients and physicians) would improve after implementation of the PtDAs. Moreover, we anticipated that physicians using the PtDAs would formulate less "treatment recommendations" during consultations. By "treatment recommendation" we refer to whether the physician formulated a specific treatment advice during the consultation. The recommendation could for instance be: "I recommend you to start single agent carboplatin chemotherapy soon." The hypothesis that use of PtDAs would decrease treatment recommendations is based on the fact that the SDM process encourages the patient to formulate a treatment decision, supported by, but not primarily adviced or decided by the physician.

In this paper we report the results of evaluations before and after the implementation of the two PtDAs with regard to: 1) observed SDM, 2) treatment recommendations formulated by physicians during the consultations, and 3) patients' and physicians' evaluations of SDM in consultations.

2. Methods

The project was conducted in collaboration between the Center for Shared Decision Making at Vejle Hospital (CSDM), the Danish Gynecological Cancer Group (DGCG), and the departments of oncology at Aarhus University Hospital, Odense University Hospital, and Vejle/Lillebaelt Hospital, University Hospital of Southern Denmark.

The PtDAs were developed in a project group including three patients with relapsed ovarian cancer (representatives from the Danish Patient Organisation for Women with Gynecological Cancer (KIU)), gynecologists, oncologists, oncology nurses, and SDM specialists. A manuscript regarding the development of the PtDAs and their implementation has been submitted for publication elsewhere.

Briefly, two PtDAs were developed, one to be used for patients suffering from platinum-sensitive relapse defined by recurrence occurring more than six months after last platinum-containing chemotherapy, and another to be used for patients suffering from platinum-resistant disease. The prognosis for the last group of patients is much worse than for patients diagnosed with platinum-sensitive disease and treatment options are few and the purpose is definitely palliative. For patients with platinum-sensitive relapse the purpose of treatment is to improve survival without symptoms of disease, and for some patients treatment induces long lasting remission of disease. Based on the fact that the platinum-free interval is both prognostic and predictive the option cards and the statistical information cards of the two PtDAs are very different. The final two PtDAs were completed after several iterative processes of face validity testing among study nurses and patient representatives and structured interviews including 10 patients and 15 physicians. The PtDAs were in paper version and based on a generic PtDA template [13,14] consisting of a booklet holding different option cards, one card per treatment option with pictograms and simple text describing the pros and cons of the option (Fig. 1). The PtDA template was developed based on Elwyn et al.'s model, including a team talk, option talk and decision talk [4]. The cover of the PtDA shows five steps guiding the consultation between patient and healthcare professional towards decision making. Step four refers to the option cards, which are chosen for the specific situation by the healthcare professional after step 1–3. The PtDAs were used in the consultations, but the patients were offered to bring them home for closer reading and discussion with relatives before decision making (step 5).

The implementation of the PtDAs at each department was decided and conducted by three dedicated project group oncologists (one at each department). Prior to implementation of the PtDAs the project group oncologists participated in different educational activities managed by the CSDM to prepare them for the task of implementing SDM and the PtDAs. At each department the project group oncologist supported by a SDM specialist from the CSDM conducted group teaching in the general principles of SDM and in the use of the specific PtDAs. These teaching sessions were conducted before but close to the implementation of the PtDAs. After the initial teaching sessions, new physicians were primarily trained in the use of the PtDAs and SDM principles by watching a more experienced physician using the PtDA in the consultation room.

The study design is a before-and-after investigation meaning that data was collected during two time periods, i.e. before and after implementation of the PtDAs (October 2018 to February 2019 and April to December 2019, respectively).

During data collection dedicated nurses at each department systematically screened the outpatient program to consecutively invite all patients with relapsed ovarian cancer to participate in the study. Suspicion of relapse was based on rising CA-125 and/or findings on CT scans.

Observed SDM was assessed by a study nurse present in the consultation room as an independent observer. One study nurse at each department was engaged part-time for the project and part time for clinical nursing tasks. Prior to conducting OPTION scoring the study nurses had been trained in the scoring procedure by an experienced OPTION rater (Olling) at the CSDM. The study nurses participated in all possible consultations when they were present in the outpatient clinic. The consultations were

Fig. 1. Patient Decision Aid used for patients with platinum-sensitive relapsed ovarian cancer.

audio-recorded and for consistency a random subset of the recordings were double-rated by an independent specialist in OPTION-rating from the study team of Olling et al. [15]. The validated OPTION instrument consists of 12 items measuring SDM behavior in consultations [16]. Each item is scored 0–4 and summed to a maximum of 48 (Table 4). In addition to the sum scores we analyzed scores of single items to show which elements of SDM changed most. Since all three study nurses were skilled in English, we used the original English version of the OPTION supported by a Danish-worded consensus-manual. An ad hoc item was included at the end of the OPTION instrument as to whether the nurse observed the physician formulate a treatment recommendation during the consultation.

The consultation process was rated immediately after the consultation using the internationally validated questionnaires CollaboRATE [17] and SDM-Q-9 [18,19] by patients and the SDM-Q-Doc by physicians [20]. All three questionnaires have been translated into Danish, but only the SDM-Q-9 has been formally validated in a Danish population [21].

CollaboRATE is a brief patient-reported measure of SDM that covers the degree of collaboration and involvement by three questions. Each item is scored on a scale from 0 to 9. According to the scoring manual, evaluation should include the number of “top scores” i.e. individuals who answered “9” to all three items and “mean scores” [22].

SDM-Q-9 is a patient-reported 9-item questionnaire measuring the degree of SDM in the consultation. It is answered on a Likert scale ranging from”completely disagree” to “completely agree” with six response options. The scores are summed and transferred into a scale ranging 0–100, with 100 mirroring superior evaluation of SDM [18].

SDM-Q-Doc measures healthcare professional-reported degree of SDM and is similar to SDM-Q-9 regarding number of items, wording, response

scale, and scoring. Prior to this study the SDM-Q-Doc was English-Danish forward and backward translated and face-validity tested by another Danish research group, but the Danish version has not been formally validated (nor published). The scoring of SDM-Q-Doc is similar to the scoring of SDM-Q-9 with the maximum score of 100 reflecting superior evaluation of SDM.

Sociodemographic and clinical information on the patients was retrieved by the local study nurse in cooperation with the physician handling the consultation. Data included number of relapses, the Eastern Cooperative Oncology Group (ECOG) Performance Status [23], cohabitant status, educational level and work status.

After the consultation the physician was asked to disclose amount of previous training in SDM.

As the study was a quality improvement project no formal sample size calculation was conducted. Based on previous experience with the PtDA template we planned to collect OPTION scores from at least 20 patients before and 20 patients after the implementation of the PtDAs.

All data was analysed within the frame of a before-and-after design. Binominal outcomes were tested using chi-square statistics. Linear, non-normalised data was analysed using the two-sample Wilcoxon rank-sum (Mann–Whitney) test.

After the overall analysis, we repeated the analysis for department (A, B and C), stratified by specialist/non-specialist and by physician being trained/not trained in SDM. These analyses were exploratory, as the before-after differences could be explained by setting, physicians' different experience in handling cancer patients, or physicians' amount of training in the principles of SDM. For the primary exploratory analyses physician SDM training was dichotomized into "No training at all" and ">0 hours of training".

STATA version 16 (StataCorp LLC, College Station, Texas, USA) was used for the analyses. Statistical significance was set to $p < 0.05$ two-sided. We did not correct for multiple comparisons.

2.1. Ethics

All patients gave written and orally informed consent. The Regional Data Protection Agency of Southern Denmark approved the study (file number 18/30213). Approval of research projects by the Committee on Health Research Ethics is required only if the project involves an intervention in the sense of the Committee Act or human biological material. Therefore, this study was conducted without any formal ethics approval according to Danish law.

3. Results

Patient characteristics are shown in Table 1 (upper part). Briefly, the median age of the patients was 69 years, the majority had ECOG performance status 0, were cohabiting, well educated (≥ bachelor), and outside the workforce. Half of the patients suffered from first relapse. The majority of patients (52%; 62 of 119) were recruited at Department B. Patient characteristics were similar across the three participating departments.

The bottom part of Table 1 shows characteristics of the physicians. The majority (14 of 24) of the physicians conducting the consultations worked at Department B. The proportion of physicians reporting no training at all in SDM differed between the departments (21% to 57%) and was lowest at Department B.

A total of 22 consultations before and 33 after implementation of the PtDAs were observed and rated according to OPTION (Table 2). Faster than expected recruitment enabled the nurses to score more than the planned 20 consultations before and 20 after implementation of the PtDAs. A random nine of 55 consultations were OPTION double-rated using the audio-recordings. These ratings differed minimally (mean difference in OPTION sum score = 1.2 points; sum of all 12 items = −4 to +1) and formal inter-rater reliability testing was deemed unnecessary.

There was a statistically significant improvement in the overall mean OPTION score from 17.8 before to 23.4 after implementation of the PtDAs ($p = 0.002$). Improvement was also statistically significant when stratifying by department. Specialists in oncology as well as non-specialists improved their OPTION score after the implementation of PtDAs, but with statistical significance for specialists only ($p = 0.028$; non-specialists $p = 0.052$). There was no significant difference in mean OPTION score between specialists and non-specialists before implementation of PtDAs. After the implementation the difference was statistically significant with a mean OPTION score of 26.2 for specialists and 19.2 for non-specialists ($p = 0.002$, data not shown). In the stratified analyses focusing on the impact of physicians being trained in SDM or not, we found a statistically significant improvement of the OPTION score in consultations conducted by physicians reported being trained in SDM (17.3 to 23.4; $p = 0.009$). Physicians not trained in SDM did also improve their OPTION score, but observations were few and the finding was not statistically significant ($p = 0.33$). As a consequence of the few data on physicians with no training, we conducted supplementary analyses where SDM training was divided in "No SDM training at all", ">0 - 2 hours of SDM training", and "> 2 hours of SDM training" (Table 3). Improvement in observed SDM was detected in consultations conducted by physicians reporting more than two hours of SDM-training (15.0 to 26.6; $p < 0.001$), but not in consultations conducted by physicians reporting some but less than two hours of training in SDM (23.3 to 20.8: $p = 0.69$).

The mean OPTION score of individual items increased statistically significantly in six of 12 (50%) items (Table 4). The most pronounced improvement was seen in item 8 "The clinician explores the patients' concerns (fears) about how problem(s) are to be managed" (+0.92; $p < 0.001$), followed by item 3 "The clinician assesses the patient's preferred approach to receiving information to assist decision making" (+0.79; $p = 0.005$), and item 7 "The clinician explains the pros and cons of options to the patient (taking´ no action is an option)" (+0.73; $p = 0.006$).

The proportion of consultations in which a recommendation was given by the physician decreased from 63.6% to 51.5%, but the difference was not statically significant ($p = 0.38$) (Table 2). At Department B a statistically significant decrease from 85.7 to 41.2% was found ($p = 0.047$).

Patient and physician evaluations were collected from 39 consultations before and 80 consultations after implementation of the PtDAs. The upper part of Table 5 shows the patient perceived level of SDM accessed by SDM-Q9 and CollaboRATE, overall and for each department. No statistically significant differences were found except for the mean CollaboRATE score at Department A with a slight decrease from 8.97 to 8.38 ($p = 0.047$). No statistically significant differences were found by stratification according to specialist/non-specialist or SDM training (lower part of Table 5 and Table 3).

There were no statistically significant differences in the mean SDM-Q-Doc scores before-after, neither overall nor in the stratified analyses (Table 5 and Table 3).

Although not shown in the tables, we did exploratory analyses on the overall before-after results stratifying the data by number of relapses (first or later) and by ECOG performance status (0 or higher) (data not shown). The improvement in the OPTION score was not statistically significant for patients suffering from second or later relapse ($p = 0.0508$). Remarkably, the mean SDM-Q-Doc score for patients suffering from first relapse differed statistically significantly with 73.07 before and 81.46 after the implementation of PtDAs ($p = 0.03$).

4. Discussion and conclusion

4.1. Discussion

4.1.1. Overall findings

This study analyzed the implementation of two paper version PtDAs in consultations with patients suffering from relapsed ovarian cancer at three Danish departments of oncology. Observed SDM according to the OPTION instrument improved statistically significantly both overall and in each of the three participating departments. Improvement was also statistically significant in the group of specialists and in the group of trained physicians.

Table 1
Characteristics of patients and physicians before and after implementation of the Patient Decision Aids.

Patients	All	Dept. A	Dept. B	Dept. C
Total	119 (100%)	31 (100%)	62 (100%)	26 (100%)
Before implementation of PtDAs	39 (33%)	11 (35%)	18 (29%)	10 (38%)
After implementation of PtDAs	80 (67%)	20 (65%)	44 (71%)	16 (62%)
Median age (interquartile range)	69 (61–74)	66 (60–73)	69.5 (63–75)	64 (60–71)
ECOG PS*				
0	66 (56%)	20 (65%)	29 (47%)	17 (65%)
1	48 (40%)	9 (29%)	31 (50%)	8 (31%)
2 (worst)	5 (4%)	2 (6%)	2 (3%)	1 (4%)
Relapse number*				
First	60 (50%)	17 (55%)	28 (45%)	15 (58%)
Second or later	59 (50%)	14 (45%)	34 (55%)	11 (42%)
Median relapse number* (Range)	1 (1–6)	1 (1–6)	2 (1–6)	1 (1–6)
Living alone				
Yes	37 (31%)	12 (39%)	17 (27%)	8 (31%)
No	82 (69%)	19 (61%)	45 (73%)	18 (69%)
Educational level				
Below Bachelor	42 (35%)	10 (32%)	22 (35%)	10 (38%)
Bachelor or higher	77 (65%)	21 (68%)	40 (65%)	16 (62%)
Employed				
Yes	11 (9%)	5 (16%)	5 (8%)	1 (4%)
No	108 (91%	26 (84%)	57 (92%)	25 (96%)
Co-morbidity				
None	54 (45%)	10 (32%)	32 (52%)	12 (46%)
One or more	65 (55%)	21 (68%)	30 (48%)	14 (54%)
Physicians	All	Dept. A	Dept. B	Dept. C
Total	24 (100%)	4 (17%)	14 (58%)	6 (25%)
Consultations				
before implementation of PtDAs only	7 (29%)	0	4 (29%)	3 (50%)
after implementation of PtDAs only	8 (33%)	0	8 (57%)	0
both before and after implementation	9 (38%)	4 (100%)	2 (14%)	3 (50%)
Women	19 (79%)	3 (75%)	10 (71%)	6 (100%)
Men	5 (21%)	1 (25%)	4 (29%)	0
Specialists	10[#] (40%)	2 (50%)	5[#] (33%)	3 (50%)
Non-specialists	15[#] (60%)	2 (50%)	10[#] (67%)	3 (50%)
SDM training				
None (% of physicians; % of consultations)	8[¤] (32%; 14%)	1 (25%; 6%)	3 (21%; 15%)	4[¤] (57%; 23%)
Reported to be trained (% of physicians; % of consultations)	17[¤] (68%; 86%)	3 (75%; 94%)	11 (79%; 85%)	3[¤] (43%; 77%)

All patient data are based on patient questionnaires except those *retrieved from patient medical chart.
[#] One physician became an oncologist (specialist) during the project; [¤] One specialist answered yes to both "trained" and "not trained"; ECOG PS: The Eastern Cooperative Oncology Group Performance Status.

The proportion of consultations where a treatment recommendation was provided did not change statistically significantly. Despite the increased level of observed SDM, patient and physician evaluations of SDM did not improve.

4.1.2. Observed SDM (OPTION scores)

The finding of improved OPTION ratings after implementation of the PtDAs was expected, as the instruments were based on a rigorous, generic PtDA platform supporting the physicians in following Elwyn's three-talk-model [4]. The model is aligned with the OPTION scale, which has been widely used in the research context of SDM [15,24].

In the supplementary analyses where physician training was divided in three strata ("No SDM training at all", ">0 - 2 hours of SDM training", and "> 2 hours of SDM training") a large (+11.6) and statistically significant improvement of the OPTION score was found in the consultations conducted by physicians reporting more than two hours of training in SDM (15.0 to 26.6; $p < 0.001$) compared to a non-statistically significant decrease in the consultations conducted by physicians reporting some but less than two hours of training in SDM (23.3 to 20.8: $p = 0.69$) (Table 3). This result implies that a certain amount of SDM training is necessary to improve the physician's SDM skills and thus the level of observed SDM in consultations. Importantly, this finding is in accordance with findings by Couët et al. in their review from 2015 on variables associated with higher OPTION scores [25]. The authors stated: "We found results hinting that clinicians trained in SDM, once they have integrated patient-involving behaviours into their practice, may continue to work this way (improved OPTION scores were sustained over time)".

Therefore, in our opinion, the stratified OPTION results underpin that implementation of PtDAs is not "tick-a-box" for SDM performed in consultations. SDM skills training is very important for the effectiveness of PtDAs and no SDM training or very little SDM training is insufficient to improve the level of observed SDM.

4.1.3. Treatment recommendations

In the present study "treatment recommendation" refers to whether the physician formulated a specific treatment advice during the consultation. Implementation of the PtDAs did not lower the proportion of recommendations in consultations overall. Neither did we find any uniform direction of change in the exploratory analyses. The findings might be explained by too little training in SDM, including no formal guidance to physicians on whether or not to offer recommendations. The use of the PtDAs may have led some patients to directly ask for the physician's personal opinion about the options discussed. Also, talking about patient preferences and values may have caused the physician to arrive at conclusions and decisions instead of waiting for the patient to be ready to formulate them.

A study by Frongillo et al. [26] focusing on SDM in breast cancer surgery found that most patients (85%) reported to having been given a treatment recommendation. Patients who did not receive a

Table 2
Observed level of SDM measured by the OPTION scale, and recommendation by physician before and after implementation of the Patient Decision Aids.

	All departments	Dept. A	Dept. B	Dept. C
	N = 22/33	*N* = 6/11	*N* = 7/17	*N* = 9/5
Mean OPTION Score*				
Before	17.8	15.2	14.9	21.8
(IQR)	(13–21)	(12–15)	(12–18)	(21–24)
After	23.4	27.7	18.2	31.8
(IQR)	(18–28)	25–32)	(16–20)	(28–37)
***p*-value** (Wilcoxon Rank Sum)	0.002	0.002	0.038	0.016
Recommendation#				
Before Yes (%)	14 (63.6%)	3 (50.0%)	6 (85.7%)	5 (55.6%)
After Yes (%)	17 (51.5%)	7 (63.4%)	7 (41.2%)	3 (60.0%)
p-value (chi2-test)	0.38	0.59	0.047	0.87

	Specialists	Non-specialists	Trained in SDM	No SDM training¤
	N = 11/20	N = 11/13	N = 11/32	N = 11/1
Mean OPTION Score*				
Before	20.1	15.5	17.3	18.3
(IQR)	(15–26)	(12–19)	(12–24)	(18–21)
After	26.2	19.2	23.4	25.0
(IQR)	(20.5–32.5)	(16–20)	(17.5–29)	(25–25)
p-value (Wilcoxon Rank Sum)	0.028	0.052	0.009	0.33
Recommendation#				
Before Yes (%)	7 (63.6%)	7 (63.6%)	7 (63.6%)	7 (63.6%)
After Yes (%)	12 (60.0%)	5 (38.5%)	16 (50.0%)	1 (100%)
p-value (chi2)	0.84	0.22	0.43	0.46

Mean OPTION scores and "recommendation given by physician" overall, and by each department, by specialist/non-specialist, and by physician being trained/not trained in SDM.

* The Mean OPTION score for individual patients was calculated as the sum of the 12 items (each item ranging 0–4).

Ad hoc item: "Did the physician formulate a treatment recommendation?" (y/n).

¤ "No SDM training" = physician reported no SDM training at all.

recommendation scored higher on involvement compared to those who did (52% vs. 39.1%, $p = 0.004$). Many clinicians consider the act of providing recommendations to be incompatible with SDM and feel reluctant to do so. On the other hand, timing and content of a recommendation might be more important than whether a recommendation is given [27]. Since in our study observers were not asked to report the context of and reason for the recommendation, our finding of no overall decrease in treatment recommendations should be interpreted with caution.

4.1.4. Patient and physician perceived level of SDM

We did not confirm our hypothesis that the PtDAs would improve patients' and physicians' perceived level of involvement in the decision making process. Neither did the stratified analyses imply any positive effect of PtDA use on perceived SDM. One could argue that if patients do not perceive improved SDM in consultations where PtDAs are used then why use them. We are still convinced that perceived SDM can be improved in oncological consultations and possibly by using PtDAs.

There are several possible causes for the negative findings. First, the introduction and training of physicians may not have been extensive enough, or as reflected by the physicians' answers, have reached too few. Another reason could be that the used instruments are insensitive to improvement in intervention studies. One reason could be the socalled "ceiling effect". At baseline, we observed high mean SDM-Q-9 scores for the total group and also when stratyfying by department, medical specialization, and SDM training. The lowest score (88.65) was found at Department B, and considering the fact that the maximum score of SDM-Q-9 is 100, this is actually not a low score. Such a "ceiling effect" makes it difficult for the instrument to detect a statistically significant improvement [28]. Ceiling effects are well described in relation to SDM-Q-9 [21].

Similar to SDM-Q-9, the baseline CollaboRATE scores were very high, leaving little room for improvement, i.e. the "ceiling effect" might also have been a problem there. CollaboRATE has been used in several Danish studies [29,30]. A study introducing SDM in lung cancer diagnostics using PtDAs based on the same template as in the current study, reported a lower baseline CollaboRATE mean score than ours (7.36 vs. 8.64). The study succeeded in showing a statistically significant CollaboRATE improvement [14].

We found no difference in SDM-Q-Doc scores, and "ceiling effects" appear to not pose a problem in this aspect (baseline score 77.60). Interestingly, in the exploratory analyses focusing on the impact of first or later relapse (data not shown), the mean SDM-Q-Doc score for patients suffering from first relapse was higher after the implementation of PtDAs (81.46 compared to 73.07 before, $p = 0.030$). Since the first relapse of the disease is typically platinum-sensitive, there are different treatment options to offer, which might leave the physician with a sense of having practised SDM to a higher extent.

Our neutral findings appear less surprising when comparing with Doherr et al.'s systematic review on the use of SDM-Q-9 and/or SDM-Q-Doc in SDM intervention studies [31]. Five studies were included and no or minimal effect of SDM interventions was found. The authors made two important statements: 1. "Interventions targeting both patients and health care professionals have been found to be more effective than single-target interventions" and 2. "A psychometric study focusing on the measure's sensitivity to change is strongly recommended."

Table 3
Observed and perceived level of SDM and treatment recommendations in consultations before and after implementation of the Patient Decision Aids analyzed by amount of SDM training.

Observed data:	All	0 h of SDM training	>0–2 h of SDM training	>2 h of SDM training
	N = 22/33	N = 11/1	*N* = 3/18	*N* = 8/14
Mean OPTION Score*				
Before (IQR)	17.8 (13–21)	18.3 (13–21)	23.3 (14–32)	15.0 (11.5–16)
After (IQR)	23.4 (18–28)	25.0 (25–25)	20.8 (16–24)	26.6 (20–32)
P (Wilcoxon)	0.002	0.33	0.69	<0.001
Recommendation[Ω]				
Before Yes (%)	7 (63.6%)	4 (36.4)	0 (0%)	4 (50%)
After Yes (%)	12 (60.0%)	0 (0%)	11 (61.1%)	5 (35.7%)
p (chi2)	0.84	0.46	0.05	0.51
Perceived data:	All	0 h of SDM training	>0–2 h of SDM training	>2 h of SDM training
	N = 39/80	*N* = 16/1	*N* = 4/36	*N* = 19/43
Mean SDMQ-9 score[π]				
Before (IQR)	92.16 (84.4–100)	88.61 (81.1–100)	93.33 (80.0–100)	94.97 (93.3–100)
After (IQR)	90.66 (84.4–100)	73.33 (73.3–73.3)	89.26 (84.4–100)	92.28 (86.7–100)
p (Wilcoxon)	0.73	0.24	0.68	0.32
CollaboRATE Top Score[#]				
Before (%)	27 (69%)	8 (50%)	2 (50%)	17 (89%)
After (%)	53 (66%)	0 (0)	23 (64%)	30 (70%)
p (chi2)	0.75	0.33	0.59	0.10
CollaboRATE Mean Score[¤]				
Before (IQR)	8.64 (8.3–9.0)	8.42 (8.0–9.0)	8.25 (7.5–9.0)	8.91 (9.0–9.0)
After (IQR)	8.50 (8.0–9.0)	6.00 (6.0–6.0)	8.50 (8.0–9.0)	8.56 (8.0–9.0)
p (Wilcoxon)	0.56	0.12	0.57	0.06
Mean SDM-Q-Doc score[π]				
Before (IQR)	77.60 (66.7–91.1)	72.00 (57.8–71.1)	70.56 (61.1–80.0)	83.83 (80.0–93.3)
After (IQR)	81.14 (76.7–91.1)	80.00 (80.0–80.0)	71.42 (61.1–80.0)	89.30 (84.4–97.8)
p (Wilcoxon)	0.18	0.63	0.73	0.13

* The Mean OPTION score for individual patients was calculated as the sum of the 12 items (each item ranging 0–4).
Ω Ad hoc item: "Did the physician formulate a treatment recommendation?" (y/n).
π For both SDM-Q-9 and SDM-Q-Doc all nine items (scored 0–5) were summed and multiplied by 100/5*9 providing a score ranging 0–100; 100 = top score.
CollaboRATE Top score: the three CollaboRATE items all scored 9, i.e. sum score = 27.
¤ CollaboRATE Mean score: the mean score of the three CollaboRATE items; minimum = 0, maximum = 9.

4.1.5. Discussion of the implementation of the PtDAs

Improved observed SDM (particularly in consultations where physicians were trained in SDM more than two hours) combined with no improvement in patient and physician evaluations of SDM draw attention to the implementation of the PtDAs. As stated in the Methods, group teaching of physicians in the principles of SDM and the use of the specific PtDAs

Table 4
Wording and scoring of the OPTION items, mean values before and after implementation of the Patient Decision Aids.

Item	SDM Behavior	Score before PtDAs						Score with PtDAs						Diff	p-value*
		0	1	2	3	4	Mean	0	1	2	3	4	Mean		
1	The clinician draws attention to an identified problem as one that requires a decision making process.	1	8	10	3	0	1.68	0	8	18	6	1	2.00	0.32	0.171
2	The clinician elicits the patient's preferred level of involvement in decision-making.	5	11	4	2	0	1.14	6	17	6	3	1	1.27	0.13	0.673
3	The clinician assesses the patient's preferred approach to receiving information to assist decision making.	6	12	4	0	0	0.91	2	16	8	4	3	1.70	0.79	0.005
4	The clinician states that there is more than one way to deal with the identified problem ('equipoise').	1	8	8	3	2	1.86	0	6	9	16	2	2.42	0.56	0.028
5	The clinician explores the patient's expectations (or ideas) about how the problem(s) are to be managed.	1	5	9	5	2	2.09	1	10	13	7	2	1.97	−0.12	0.648
6	The clinician lists 'options', which can include the choice of 'no action'.	1	8	7	6	0	1.82	1	9	8	14	1	2.15	0.33	0.207
7	The clinician explains the pros and cons of options to the patient (taking 'no action' is an option).	2	4	11	4	1	1.91	0	1	15	12	5	2.64	0.73	0.006
8	The clinician explores the patient's concerns (fears) about how problem(s) are to be managed.	6	10	4	1	1	1.14	0	9	15	7	2	2.06	0.92	<0.001
9	The clinician checks that the patient has understood the information.	5	14	3	0	0	0.91	1	19	11	0	2	1.48	0.58	0.008
10	The clinician offers the patient explicit opportunities to ask questions during the decision making process.	0	9	9	0	4	1.95	1	17	5	3	7	1.94	−0.01	0.639
11	The clinician indicates the need for a decision making (or deferring) stage.	3	12	6	1	0	1.23	4	13	8	5	3	1.70	0.47	0.163
12	The clinician indicates the need to review the decision (or deferment).	4	12	4	2	0	1.18	3	12	7	7	4	1.91	0.73	0.024

Scoring: 0: The Behavior is not observed; 1: A minimal attempt is made to exhibit the behavior; 2: The behavior is observed and a minimum skill level achieved; 3: The behavior is exhibited to a good standard; 4: The behavior is exhibited to a very high standard
* two-sample Wilcoxon rank-sum (Mann–Whitney) test.

Table 5
Patient and physician perceived degree of shared decision making in consultations before and after implementation of the Patient Decision Aids.

	All	Dept. A	Dept. B	Dept. C
	N = 39/80	**N = 11/20**	***N* = 18/44**	***N* = 10/16**
Mean SDM-Q-9 score*				
Before (IQR)	92.16 (84.4–100)	95.15 (93.3–100)	88.64 (80.0–100)	95.56 (97.8–100)
After (IQR)	90.66 (84.4–100)	91.58 (82.2–100)	93.23 (87.8–100)	82.50 (78.9–100)
p-value (Wilcoxon)	0.73	0.22	0.11	0.14
CollaboRATE Top Score[#]				
Before (%)	27 (69%)	10 (91%)	11 (61%)	6 (60%)
After (%)	53 (66%)	12 (60%)	28 (64%)	13 (81%)
p-value (chi2)	0.75	0.07	0.85	0.24
CollaboRATE Mean Score[¤]				
Before (IQR)	8.64 (8.3–9.0)	8.97 (9.0–9.0)	8.46 (8.0–9.0)	8.60 (8.3–9.0)
After (IQR)	8.50 (8.0–9.0)	8.38 (7.8–9.0)	8.48 (8.0–9.0)	8.71 (9.0–9.0)
p-value (Wilcoxon)	0.56	0.0472	0.88	0.40
Mean SDM-Q-Doc score*				
Before (IQR)	77.60 (66.7–91.1)	84.44 (71.1–93.3)	72.35 (60.0–82.2)	80.49 (66.7–97.8)
After (IQR)	81.14 (76.7–91.1)	93.56 (90.0–100)	73.13 (63.3–83.3)	87.64 (82.2–95.6)
p (Wilcoxon)	0.18	0.07	0.67	0.51
	Specialists	Non-specialists	Trained in SDM	No SDM training[Ω]
	N = 20/59	N = 19/21	*N* = 23/79	N = 16/1
Mean SDMQ-9 score*				
Before (IQR)	94.85 (93.3–100)	89.47 (80.0–100)	94.75 (93.3–100)	88.61 (81.1–100)
After (IQR)	90.73 (84.4–100)	90.48 (84.4–100)	90.88 (84.4–100)	73.33 (73.3–73.3)
p (Wilcoxon)	0.31	0.91	0.18	0.24
CollaboRATE Top Score[#]				
Before (%)	15 (75%)	12 (63%)	19 (83%)	8 (50%)
After (%)	42 (71%)	11 (52%)	53 (67%)	0 (0%)
p-value (chi2)	0.74	0.49	0.15	0.33
CollaboRATE Mean Score[¤]				
Before (IQR)	8.78 (8.8–9.0)	8.49 (8.0–9.0)	8.80 (9.0–9.0)	8.42 (8.0–9.0)
After (IQR)	8.59 (8.3–9.0)	8.24 (7.3–9.0)	8.53 (8.0–9.0)	6.00 (6.0–6.0)
p (Wilcoxon)	0.56	0.43	0.13	0.12
Mean SDM-Q-Doc score*				
Before (IQR)	82.59 (68.9–93.3)	72.87 (66.4–88.9)	81.41 (68.9–93.3)	72.00 (57.8–80.0)
After (IQR)	84.37 (77.8–95.6)	72.06 (71.1–80.0)	81.15 (75.6–91.1)	80.00 (80.0–80.0)
p (Wilcoxon)	0.72	0.53	>0.99	0.63

SDM-Q-9 Mean Scores, CollaboRATE Top and Mean Scores, SDM-Q-Doc Mean Scores, and differences analyzed overall, by department, by specialist/non-specialist, and +/− training in SDM.
IQR: Interquartile range.
* For both SDM-Q-9 and SDM-Q-Doc all nine items (scored 0–5) were summed and multiplied by 100/5*9 providing a score ranging 0–100; 100 = top score.
[#] Top score: the three CollaboRATE items all scored 9, i.e. sum score = 27.
[¤] Mean score: the mean score of the three CollaboRATE items; minimum = 0, maximum = 9.
[Ω] "No SDM training" = physician reported no SDM training at all.

was conducted at the time of the implementation of the PtDAs at all three departments. The content and format of the group teaching was not specified, but organized by the local project oncologists. Several non-specialists conducted consultations after implementation of PtDAs. As non-specialists are residents in oncology working for short time periods in each team, it is very likely that only a few non-specialists participated in the initial teaching sessions. Conclusively, effectiveness of the PtDAs was possibly limited by non-standardized and not ongoing teaching and training in the use of the PtDAs. Another limitation was that oncological nurses were not invited to the formal teaching sessions, since nurses always participate in consultations where treatment decisions are discussed.

Implementation of PtDAs is not an easy task. First, developing and regularly updating relevant PtDAs is time consuming. Second, SDM practice is closely connected with skills and with the culture and attitude among physicians and other healthcare personnel. These fundamental issues need to be addressed to guide further progress. Systematic training of the entire healthcare team in SDM knowledge and skills is important [32]. Internationally, several SDM training programs for healthcare professionals have been developed. A recent review identified 148 programs from 1996 to 2015 and reported an increasing activity (174%) in SDM training programs over four years, although few of them have been evaluated [33]. In Norway, a comprehensive SDM training curriculum has been developed for healthcare teams adapted from an evidence-based German training program. Evaluation of this training program showed a significant increase in SDM knowledge [34].

4.1.6. Strengths and limitations

The use of validated questionnaires and the inclusion of two PtDAs developed in accordance with the International Patient Decision Aids Standards (IPDAS) [35] were major strenghts of this study. The PtDAs were based on a generic template developed by the CSDM [13,36,37] following the IPDAS criteria [35,38]. The template has been used in several other studies [14,29,39]. As recommended in the IPDAS the specific content and wording of the PtDAs were established in a multidisciplinary setting, including patient representatives, and they were pilot-tested and revised before implementation. Another strength was that dedicated nurses systematically screened the outpatient programs for eligible patients. It was a limitation that the study was not designed to systematically collect data

from non-participants meaning that selection bias could be a problem for generalizability of the findings. The group of participating physicians not being exactly the same before and after implementation of the PtDAs is clearly a limitation, although it is a natural consequence of different physicians in residency during the two time periods. Since the study was designed as a quality improvement project, a rigorous sample size calculation was not conducted. The before-and-after design in itself leaves questions of causality. The randomized controlled design, which is the gold standard for analyzing effectiveness of new treatments and interventions [40], would have been very costly and logistically complicated in the present setting. The reporting by physicians on amount of training in SDM was based on one single question with categorical response options. Unfortunately, it is not possible to obtain additional information regarding the training and experience of the physicians in SDM. Furthermore, it would have been interesting to have included an outcome measure focusing on the patients' understanding of the options and their awareness of what mattered most in the decision making process, e.g. by using the Decisional Conflict Scale [41]. It is a limitation that nurses were only asked for their dichotomized evaluation as to whether a specific treatment recommendation had been formulated in the consultation. Moreover, a definition of "treatment recommendation" was not provided and nurses were not asked for information on the type and context of recommendations provided.

4.2. Innovation

Little evidence exists regarding the effects of PtDAs used in oncological consultations with cancer patients [42]. This study is innovative as it presents evidence across three different hospitals regarding the use of PtDAs in consultations with patients suffering from relapsed ovarian cancer.

Discussing oncological treatment options with the use of PtDAs is not standard practice in Denmark. In a Danish perspective, this study is innovative as it is one of the first to develop and implement PtDAs focusing on oncological treatment. The study is the first to present effectiveness of PtDAs used in oncological consultations with Danish ovarian cancer patients.

4.3. Conclusion

The purpose of the present study was to analyze if implementation of PtDAs in consultations with patients suffering from ovarian cancer would improve observed and perceived SDM. After implementation of the two PtDAs a statistically significant improvement in observed SDM was found. Supplementary analyses indicated that at least two hours of physician SDM training was necessary for improved observed SDM. Patient and physician evaluations of SDM during consultations did not improve after implementation of the PtDAs. Neither did we find a decrease in treatment recommendations.

Future initiatives focusing on how to improve SDM should be aware that introducing PtDAs does not automatically lead to SDM as perceived by patients and healthcare professionals. We believe that training of health professionals in the principles of SDM and the use of PtDAs should be an integral part of future SDM implementation initiatives. Moreover, we propose that future SDM implementation strategies incorporate organizational and structural characteristics as well as information on patients and healthcare providers.

Author contributions and dataset

KDS and LF wrote the protocol and applied for funding with the Danish Cancer Society. The statistical analysis and the first draft of this paper was done by CNW. KO was project leader during study initiation. All co-authors revised and approved the final version of this paper.

The data supporting the findings of this study are available from the Center for Shared Decision Making, Lillebaelt Hospital Vejle, Denmark. Restrictions apply according to Danish law and the data are not publicly available. Upon reasonable request to the authors relevant data can be made available.

Declaration of Competing Interest

None.

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