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ORIGINAL ARTICLE

Decisional conflict scale in metastatic colorectal cancer patients using an Arabic decision aid versus usual care: a multicenter randomized controlled trial

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ABSTRACT

Background: Shared decision-making is an essential part of patient care. Patients need more information to support their decision-making about treatment options. An Arabic language decision aid (DA) for metastatic colorectal cancer patients (mCRC) was developed, considering systemic therapy (chemotherapy with or without targeted therapy) as a choice of treatment to assess its role in patients' decision-making.

Methods: A multicenter randomized controlled trial was conducted in four out patients in oncology clinics in Saudi Arabia to measure patient certainty when selecting their treatment options and the satisfaction and willingness of oncology physicians using the Arabic DA among mCRC patients.

Results: Ninety-two patients with mCRC considering first-line systemic therapy were randomly allocated to the intervention arm (DA with usual care) or control arm (usual care alone). The outcome measured the patients' certainty regarding their decision: Decisional Conflict Scale (DCS). 51 (55%) were randomized to the DA arm. Both arms scored low in the DCS, with less than 40 (score range 1-100). However, the DA arm scored lower (range 15.1-24.3), on the overall DCS and the DCS sub-scores than the usual care arm (18.8 and 37.6). The values clarity subscale was significantly lower in the DA arm (p = 0.030).

Conclusion: This trial found significant difference with the DA's use in mCRC patients' rate of decisional conflict in the domain of clarity lower than patients receiving usual care, which could enhance a patients' ability to make treatment-related decisions. Our recommendation is to include the DA with usual care for mCRC patients as a part of the initial consultation to support shared decision making.

Keywords: Colorectal neoplasms, decision support techniques, decisional conflict, shared decision making, patient care management, decision aid.

Introduction

In Saudi Arabia (SA), colorectal cancer (CRC) is the most common cancer in men and the third most common cancer in women [1]. Previous studies have reported that 28.2% of CRC patients were diagnosed with distant metastasis [2]. Information about cancer prognosis, especially with the modest benefits of available treatments, can be complex; therefore, decisions cannot always be made easily [3]. Traditional physician-patient encounters are not free of difficulties, especially when communicating information to cancer patients [4]. Therefore, patients need to be equipped with accurate information about their disease, prognosis, and treatment options to make an informed decision[4]. A clear explanation of their condition can help increase patients' positive involvement in making decisions about treatment options [4].

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Healthcare providers support their patients to make a decision when multiple choices are available. This process, called shared decision making (SDM), involves providing knowledge, identifying risks and benefits, and incorporating values and life preferences. SDM is an integral part of medical care. SDM is "an approach where clinicians and patients share the best available evidence when faced with making decisions, and where patients are supported to compare options to achieve informed preferences" [5]. In a situation in which patients and their families face grave consequences, this can help overcome this traditional communication difficulty [6].

Clinicians, as healthcare providers, can find it challenging to share details on terminal prognoses openly or may lack the essential communication skills to do so. This difficulty is compounded by the health practice setting in SA, where medicine is practiced in English in an Arabic-speaking population; the language barrier and dealing with statistics regarding cure rate and survival rate are the main domains of difficulty [7]. Due to these difficulties in sharing information with cancer patients, several studies from the US and industrial Europe have studied other ways of transferring information to cancer patients that can help them to participate in SDM. One common strategic solution was the development of a decision aid (DA) [8].

DAs have been developed to support patients to make informed choices and enhance counseling by health professionals [3]. Cancer-related DAs have progressed over the last few years, and there is an extensive variation in both design and existing data [9,10]. DAs differ from conventional educational materials in that they present options, risks, and benefits, using quantitative and qualitative information, and involves patients in treatment decision-making with consideration of their values and preferences [9].

The literature has shown that patients' actual decision is not affected by DAs but rather decreases patients' decisional conflict, so they are more satisfied with their decision and have a more accurate perception of the risks [11]. It has also been found that patients can be empowered to make decisions if DAs are put into practice more often [12].

A Cochrane review found that DAs' implementation reduces decisional conflict associated with a lack of information and unclear values compared to usual care [10]. The use of DAs among cancer patients has been reported to improve decision-making processes [13].

The DA tool is available in many languages across the US and Europe for clinical use; however, it has not been tested in an Arabic-speaking population to the best of authors' knowledge. The need for translated versions has been addressed in some studies [14]. This is especially necessary for the Arabic language as one of the most common languages globally [15].

Our published study, on the same sample population, on effects of an Arabic DA [16] on patient anxiety and understanding compared to usual care, found that a higher level of patient's baseline understanding lowered anxiety levels over time, whereas the DA arm (DA with usual care) presented lower anxiety levels over time than the study arm provided only with usual care.

Another essential area to evaluate in patient decision-making is decisional conflict. Decisional conflict is defined as "uncertainty about what option to choose when decisions involve risks and potential losses", and may affect decision making [17]. Although studied less frequently than overall survival, disease-free survival, response rate, and quality of life, its outcome has shown validity and reliability [18].

The Decisional Conflict Scale (DCS) is the most widely used scale related to decision making. The DCS has been translated into multiple languages with four versions, three of those for use in research. The two most commonly used DCS are the traditional 16-item, five-subscale DCS has been used in most studies (around 60% of studies) and the 10-item, four-subscale low literacy DCS (DCS-LL) version (used in under 10% of studies) [18]. An essential selection criterion for this randomized control trial (RCT) was considering our overall study population regarding literacy. Our previously published results show that 17% of our study population was illiterate, and 36% had less than a high school education [16]. The research suggests that people with lower educational levels are more likely to have less knowledge of cancer, have low health literacy, worse health outcomes, and higher decisional conflict, and are less likely to make informed decision making [19]. Patients with lower education levels are likely to find it harder to complete the traditional 16-item DCS [20]. DCS-LL is easier to administer and is an acceptable alternative for use in patients with low literacy skills [18,20,21].

This study measured patient certainty when selecting their treatment options, using 10-items DCS-LL [17]. The satisfaction and willingness of oncology physicians using the Arabic DA among metastatic colorectal cancer patients (mCRC).

This RCT evaluated patients' decisional conflict between the experimental group (Arabic DA and usual care) and the control group (usual care). We measured patients' certainty when selecting their treatment options, knowing the risks/benefits, and receiving support [21]. The satisfaction and willingness of oncology physicians using the Arabic DA for mCRC patients were also measured.

Subjects and Methods

The effect of an Arabic DA tool (decision support intervention) on mCRC was evaluated through a two-arm multi-centered RCT in four public hospitals in two cities (Riyadh and Dammam). The study was initiated in March 2016, with the last follow-up completed in April 2019.

We conducted the study following the consolidated standards of reporting trials checklist. The trial attained the institutional review board ethical approvals from King Fahad Medical City (KFMC), Riyadh; King Khalid University Hospital (KKUH), Riyadh; King Saud Medical City (KSMC), Riyadh; and King Fahd Specialist Hospital, Dammam (KFSH-D). The trial ISRCTN registry number is 12269812.

Eligible patients were between the ages of 21 to 75, with a confirmed diagnosis of metastatic adenocarcinoma of the colon or rectum. Patients were excluded if 1) both they and their companions could not read or write, 2) they had previously taken or at the time of the study were not a candidate for systemic therapy (chemotherapy with or without targeted therapy), 3) had less than 6 weeks life expectancy, 4) had an uncontrollable condition that impaired decision making, or 5) had a severe comorbid illness.

Eligible patients were identified during their first oncology clinical referral visit based on study criteria. Each potential participant was informed about the study's purpose, the procedures involved, and the potential risks and benefits. After obtaining the written consent from each patient willing to participate, patients were allocation based on a pre-determined computer-generated stratified randomization study number list. The randomization list was created for each study site, to either the experimental group (Arabic DA and usual care) or the control group (usual care). The RCT design did not require the health care providers and participants to be blinded due to the nature of the study, as the DA is presented in the form of video-based tool intervention.

Usual care involved consultation with the medical oncologist, who discussed the disease, treatment options, and alternatives. After the consultation, patients were provided with additional information and educational materials; participants allocated to the experimental arm were also presented with the DA. The DA, similar to usual care, was only presented during the first initial consultation. Those receiving the DA were counseled not to share it with others in the waiting room to avoid contamination of information with those allocated to the control arm. At the next visit, 1 week later, a one-time measurement was taken on participating patient's decision conflict (the other corresponding measurements are taken, as mentioned above, can be found in Alsagheir et al. [16] study.

The Arabic language DA was developed on an iPad with infographics presented to patients regarding their treatment options (systemic therapy or no systemic therapy), outcomes (recurrence or not); the probability of outcomes and their meaning; and quality of life associated with treatment choice and outcome. Treatment option outcomes presented were data on treatment benefit, response rates, and survival rates through graphic illustrations and numeric estimates. The types of medication and their side effects were presented as well. The research team developed and formatted the DA following the Ottawa Decision Support Framework [22].

The study measured both patient certainty with decision-making and physician satisfaction in using a DA. Patient certainty with decision-making was assessed using the 10-item, four-subscale DCS-LL version [8,9]. The Decisional Conflict Instrument was translated to Arabic by three independent bilingual researchers until a group consensus was reached and then back-translated by a 4th bilingual researcher.

The decisional conflict subscale consists of four items regarding satisfaction with decision making (being informed, reflective of patients' values, likelihood to comply, and satisfied) followed by a 3-point responsive category "Yes, Unsure or No". The 3-point responsive category was selected to ensure the inclusive opportunity of the study population with low or high-level reading and response-ability.

The outcome measure consisted of 10 questions on choice and awareness of treatment options, benefits, and risks. The responses were scored and interpreted into a total score and four sub-scores (uncertainty, informed, values clarity, and support). Each response option was given a value; 0 for yes; 2 for unsure, and 4 for no. The collective responses were added to the total score, and four sub-scores were extracted from individual responses grouped and then multiplied by 25. The scores ranged from 0 to 100; the lower the score, the lower the decisional conflict [16].

The physician satisfaction tool was used to evaluate the providers' willingness to use a DA tool as a supportive decision-making tool alongside usual care. The survey used was developed from two different studies [23], split into six sections: Physician's characteristics, development of the DA, content and format of the DA, DA meeting patient's needs, physicians clinical practice, and willingness to use the DA.

The tool surveyed 15 oncologists from 3 of the study locations prior to initiating the RCT recruitment. Each participating physician was provided a demonstration of the educational DA video and then filled in their technical background, satisfaction with the content, patient benefit, and willingness to introduce the DA within their clinic.

To ensure the study is adequately powered to answer the research question, 90 patients were needed to be accrued. The primary outcome variable in the study was the level of difficulty in decision making measured by the DCS with 10 items each with a score of (0 for "yes", 2 for "unsure" and 4 for "no") with a minimum score of 0 and maximum of 40. At 5% level of significance, to detect a difference of 15% in the mean DC score between DA and usual care by at least six points (approximately 15% = 6/40) with a standard deviation of 10 and to achieve a power of 80%, the required sample size from each randomization group is four (Figure 1).

Descriptive statistics describe the patient population, including frequencies and percentages for categorical data, mean, and standard deviation for numerical data. A Chi-square test was used to compare each item of the DCS between the two arms. An independent *t*-test was used to compare the average DCS score and its domains between the two arms. Multivariate analysis was performed using the general linear model to adjust the mean difference between DCS scores and their domains by patients' baseline characteristics. Statistical analysis was performed by using IBM SPSS Statistics for Windows, Version 24.0. Armonk, NY: IBM Corp. A test was declared statistically significant if p-value < 0.05.

Results

The sociodemographic characteristics of the two groups are shown in Table 1. The mean age of participating

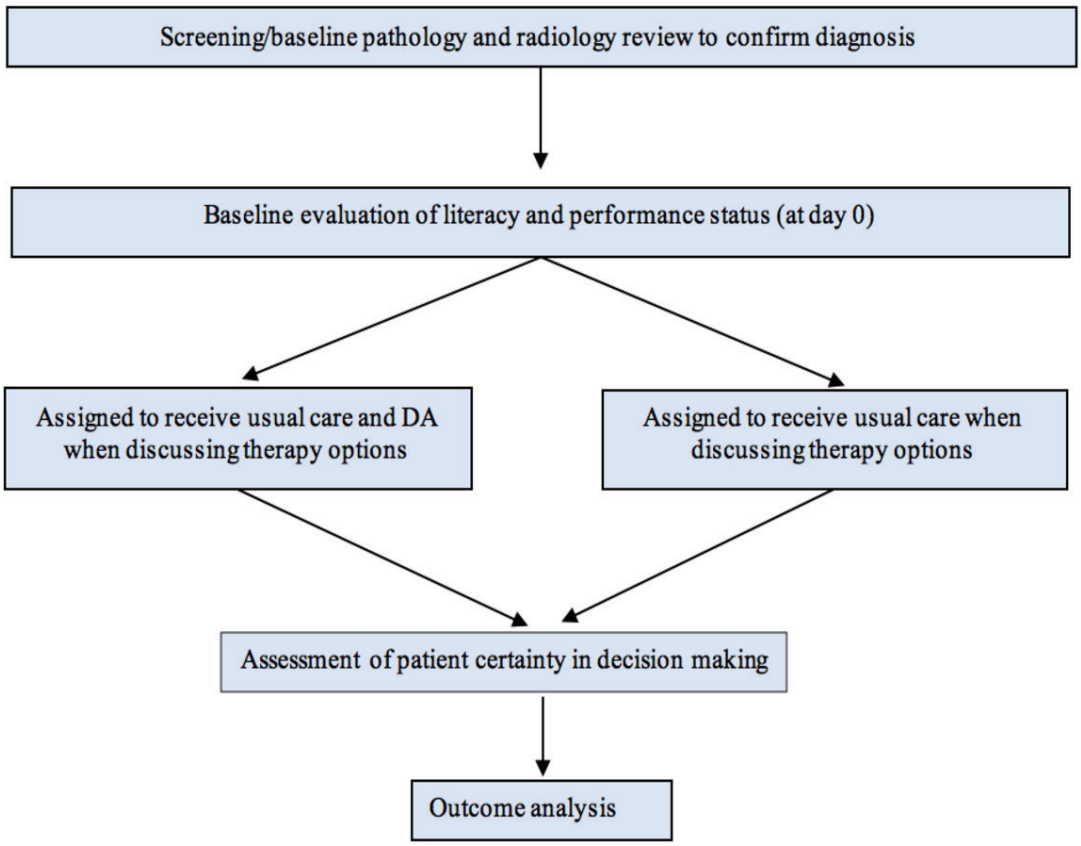

Figure 1. *Flowchart showing the study scheme.*

Table 1. *Sociodemographic characteristics by randomization group.*

		Randomization group					
		Decision aid (n = 51)		Usual care (*n* = 41)		Total (*n* = 92)	
		N	%	*N*	%	*N*	%
Age (years)	Mean SD	55.3 ± 11.9		57.0 ± 12.8		56.1 ± 12.3	
Gender	Male	37	72.5	25	61.0	62	67.4
	Female	14	27.5	16	39.0	30	32.6
Marital status	Married	34	66.7	32	78.0	66	71.7
	Single	10	19.6	5	12.2	15	16.3
	Divorced	4	7.8	0	0.0	4	4.3
	Widowed	3	5.9	4	9.8	7	7.6
Residence distance (km)	Within 50	26	52.0	19	46.3	45	49.5
	50-100	9	18.0	7	17.1	16	17.6
	100-200	3	6.0	3	7.3	6	6.6
	200-400	4	8.0	2	4.9	6	6.6
	>400	8	16.0	10	24.4	18	19.8
Education	Illiterate	6	11.8	10	24.4	16	17.4
	Less than high school	20	39.2	13	31.7	33	35.9
	High school	9	17.6	7	17.1	16	17.4
	Diploma	6	11.8	6	14.6	12	13.0
	College graduate	9	17.6	5	12.2	14	15.2
	Post graduate	1	2.0	0	0.0	1	1.1
Monthly income (SAR[a])	<5,000	14	27.5	15	36.6	29	31.5
	5,000-10,000	25	49.0	16	39.0	41	44.6
	10,001-15,000	8	15.7	5	12.2	13	14.1
	>15,000	4	7.8	5	12.2	9	9.8

a: 1$ = 3.75SAR. SD: standard deviation.

Table 2. *DCS for all patients.*

	Yes		Not sure		No	
	N	%	*N*	%	*N*	%
Do you know which options are available to you?	48	55.8	17	19.8	21	24.4
Do you know the benefits of each option?	55	63.9	15	17.4	16	18.6
Do you know the risks and side effects of each option?	52	60.4	16	18.6	18	20.9
Are you clear about which benefits matter most to you?	59	68.6	14	16.3	13	15.1
Are you clear about which risks and side effects matter most to you?	64	74.4	11	12.7	11	12.7
Do you have enough support from others to make a choice?	71	82.6	11	12.7	4	4.7
Are you choosing without pressure from others?	68	79.1	8	9.3	10	11.6
Do you have enough advice to make a choice?	55	63.9	20	23.3	11	12.7
Are you clear about the best choice for you?	58	67.4	13	15.1	15	17.4
Do you feel sure about what to choose?	58	67.4	15	17.4	13	15.1

Table 3. *A multivariate model of the decisional conflict scale and its domains by randomization groups and baseline characteristics.*

Domain	Unadjusted mean difference	*p*-value[a]	Adjusted mean difference	95% CI for B		*p*-value[b]
				Lower	Upper	
DCS	−9.3	0.066	−10.8	−21.7	0.2	**0.054**
Uncertainty	−8.5	0.285	−9.6	−27.0	7.8	0.273
Informed	−13.3	0.079	−13.7	−30.4	2.9	0.104
Values clarity	−13.1	0.074	−17.8	−33.9	−1.7	**0.030**
Support	−3.2	0.535	−3.9	−15.1	7.3	0.489

Mean difference = (DA-usual aid).

[a]Unadjusted *p*-value using independent *t*-test.

[b]Adjusted mean difference of scale between decision aid versus. Usual care (variables included in the model: age, gender, marital status, residence distance (km), education, and monthly income (SAR); 2 adjusted *p*-value.

Bold text indicates a statistically significant difference with a *p*-value less than 0.05.

patients was 56.1 (12.3), with almost two-thirds were males. Most of the patients were married, and nearly half of both groups lived within 50 km of the health facility with a monthly income of 10,000 Saudi Riyals or less. However, none of the sociodemographic characteristics were found to be statistically significant between the two arms (the minimum *p*-value was for marital status was $p = 0.23$).

Table 2 shows the distribution of the DCS for all patients. More than half of the patient participants reported yes to the question "Do you know which options are available to you," (56%), followed by "Do you know the risks and side effects of each option?" (64%). Questions on support unit role found the majority reported yes to: "Do you have enough support from others to make a choice" (83%) and "Choosing without pressure" (79%).

Table 3 shows both adjusted and unadjusted mean differences in the DCS and its domains by randomization groups. In general, the DA group scored lower than the usual group in the overall DCS and its subscores. The means of overall DCS scores were 19.1 (22.1) and 28.3 (24.2), ($p = 0.066$) for DA and usual care, respectively. Adjusted means were based on a general linear model by comparing the two randomization groups in the presence of other factors (baseline characteristics), which included: age, gender, marital status, residence distance (km), education, and monthly income (SAR). There was no difference between adjusted and unadjusted mean differences for most domains, indicating successful randomization. After adjustment, the overall DCS still found borderline for the DA group scored lower than usual care on average by 9.3 ($p = 0.054$). Only one domain of the adjusted means for the DCS, values clarity, was still significantly lower for the DA group than the usual care group by 17.8 ($p = 0.030$).

The mean age of the 15 participating oncologists was 43 years old; most of them are male 13 (87%) with an average of 11 years of experience. The survey found that 93% were either comfortable or very comfortable using the DA, and 69% would be very likely and 31% likely to use it if available in the next three months. Overall, physicians' satisfaction with the DA was high ≥ 80% on most items, except for "encouraging the use of

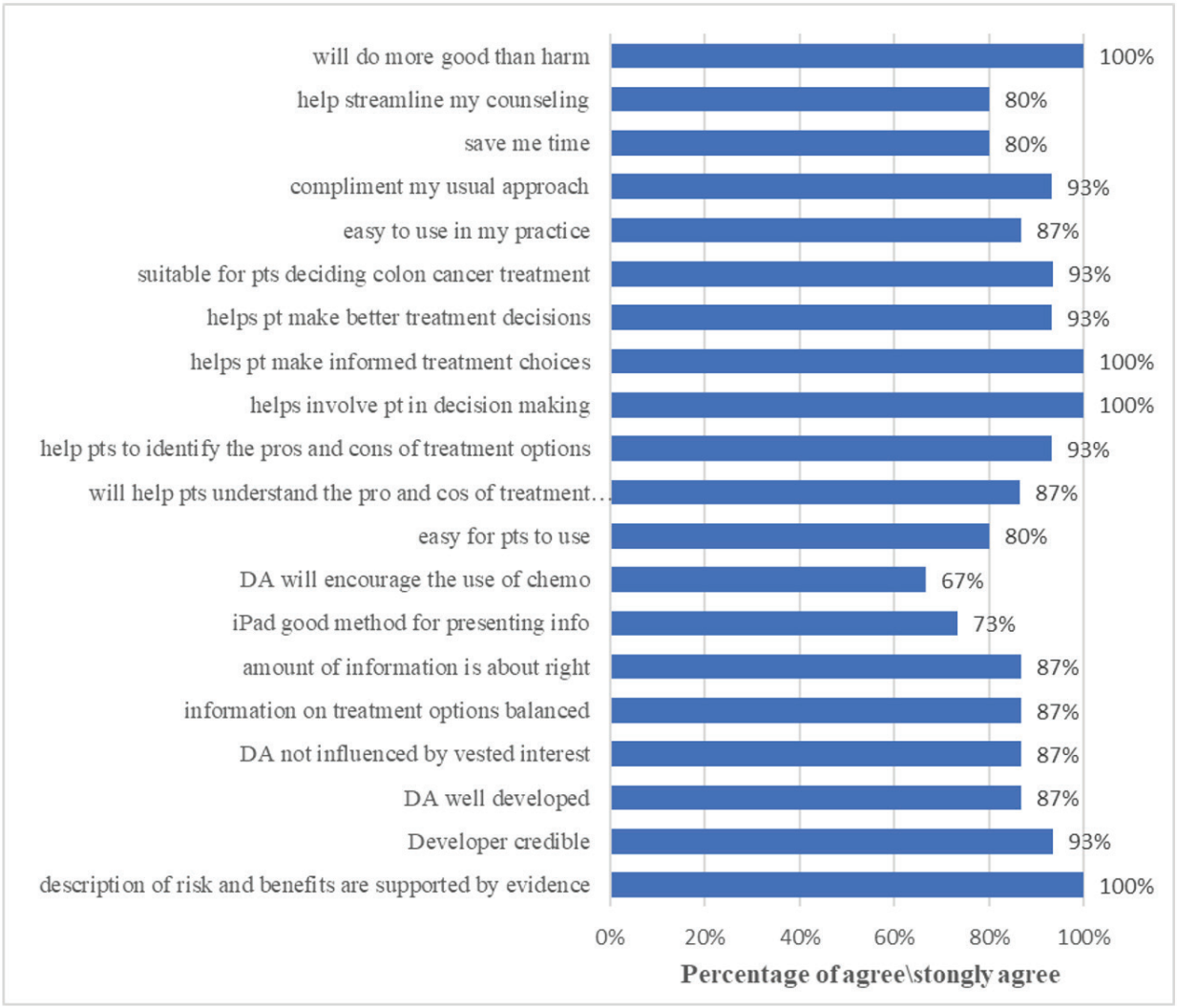

Figure 2. *Physician's level of satisfaction about the DA.*

chemotherapy" (66.7%) and "the DA was a good way for presenting information" (73.3%) (Figure 2).

Discussion

This study aimed to evaluate the DA's effectiveness on the decisional conflict in an Arabic-speaking population with newly diagnosed and previously untreated mCRC and evaluate physicians' satisfaction with the DA.

A systematic review reported that two-thirds of patients with advanced cancer wished to be actively involved in decision-making [24]. With an increasing number of treatment options available, it has become increasingly difficult for patients with cancer to make treatment-related decisions [25]. Patients with cancer reported feeling uncertain, fearful, and overwhelmed about the best course of action [25]. The high decisional conflict has been associated with delayed treatment-related decisions and inferior outcomes [21]. Reducing decisional conflict has been associated with improved decision quality [21].

In our study, around 25% of patients reported being unaware of available treatment options, and about 20% stated that they were unaware of the benefits and risks of those options.

Patients in the DA group reported lower decisional conflict compared to the control group, demonstrated by the lower DCS scores and its sub scores in the DA group compared to the control group (usual care), which may encourage its evaluation for use in other conditions. There was a significantly higher understanding of the risks and benefits (value clarity) in their options, with a non-statistical trend showing less uncertainty in the total DCS.

Consistent with previous studies targeting patients with early-stage cancers who face decisions on competing treatment options, our study showed that DA reduces decisional conflict [26]. A recent systematic review has demonstrated similar results among patients in the emergency department. The decision support tool has significantly improved patient knowledge of their disease and reduced the decision-making conflict [27].

Around half of the patients and their families had not received any education about systemic therapy, which would render the physician's consult the only source of information. The knowledge gap indicates that not only are they limited to clinic sourced information on their prognosis and options, but other sources such as

nurses and health educators have not been provided previously.

The computerized DA was built utilizing the iPad and using audiovisuals to simplify complex information about the mCRC diagnosis and consequences of therapy. It achieved high acceptance by independent oncologists, supporting the findings of other studies [28], with the majority agree that it helps the patient make informed decisions, and the information provided is evidence-based. Although all surveyed physicians agreed it helps patients make informed choices, two-thirds agreed that the DA would encourage systemic therapy. This may be due to the DA presenting the side effects of systemic therapy in detail, and hence some patients may not choose to take systemic therapy.

The literature found potential barriers to the widespread use of DAs are multifaceted, including physician motivation and practice behavior, physician confidence in their verbal communication skills, lack of time, and lack of extra rooms where patients can use the DA. Motivating physician behavioral change and addressing other barriers may facilitate the wider implementation of DAs in clinical practice [29]. Local oncologists' positive response is encouraging to limit potential barriers in introducing the DA in the clinical setting. Further evaluation would be essential to assess the process of introducing the DA into routine clinical care.

Strengths of our study include developing a language appropriate DA targeting the Arab population to provide personalized and culturally sensitive recommendations as well as careful attention was made when the DCS was translated into Arabic, using forward-translations and back-translations, to allow adaptation in the Saudi culture while maintaining the meaning and content of the original DCS.

The DCS-LL is less precise than the more widely used traditional DCS. Although there is limited data on the use and the psychometric properties of the DCS-LL, it is considered an acceptable alternative for populations with low literacy skills, such as our patient population [20].

This project also met several challenges due to the length and nature of the RCT that are considered limitations in the study. The RCT took place in some of the region's major oncology centers. However, due to the specific eligibility criteria (systemic therapy naïve, stage 4, candidate for systemic therapy, consent to receive systemic therapy, literate, etc.) the estimated sample size was set small to less than 100, as such proved to be a limitation during recruitment. To overcome this, our group endeavored to collect data from almost the entire study population and to interpret the results carefully with special attention to the confidence intervals and *p*-values.

Slow recruitment is a major challenge in clinical trials. According to one report, more than 80% of clinical trials fail to be on schedule for the target population [30]. The dependency of validated coherent data on national disease burden was limited and overestimated the annual registration of newly diagnosed mCRC patients. This overestimation of annual cases that met the study eligibility criteria, led to an additional year of recruitment alongside an interesting pause between Ramadan and Hajj's months, with a lack of any newly diagnosed patient referrals. The cause can only be speculated and would require further evaluation to improve recruitment, and success of clinical trials

The Arabic DA is a supportive tool for our patient population, who are at higher risk of low health literacy and poorer outcomes, to clarify their values. The DA was found to reduce the study populations' decisional conflict and improve their ability to make decisions. Moreover, most of the physicians surveyed were comfortable using the DA and are more likely to use it if available in the future.

Conclusion

The study RCT supports the use of the DA in clinical practice to improve clarity in decisional conflict to increase patients' understanding of their disease and the available treatment options. Further research is recommended to identify patients with other cancers, who may have a higher risk for decisional conflict and lower self-efficacy in decision making to introduce patient-centered interventions. As well as larger scale studies to further assess the benefit of SDM to promote a patient centered approach.

List of Abbreviations

CRC	Colorectal cancer
DA	Decision aid
DCS	Decisional conflict scale
DCS-LL	Low literacy DCS
mCRC	Metastatic colorectal cancer
SA	Saudi Arabia
SDM	Shared decision-making

Conflict of interest

The authors declare that there is no conflict of interest regarding the publication of this article.

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Consent to participate

Written informed consent was obtained from all the participants.

Ethics approval

The trial attained the institutional review board ethical approvals from KFMC, KKUH, KSMC, KFSH-D (#ONC0300: Date December 16, 2014).

Clinical Trial Registration

The trial ISRCTN registry number is 12269812.

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