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Original Paper

Effect of Shared Decision-making on Decisional Conflict and Uptake of First-trimester Screening Tests

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ABSTRACT

Introduction: Several factors influence women's decision to take First Trimester Screening (FTS) tests. These factors are associated with the ambivalence of women toward undergoing screening tests.

Objective: This study aimed to investigate the effect of Shared Decision-Making (SDM) about undergoing FTS on Decisional Conflict (DC) immediately after consultation and uptake of FTS.

Materials and Methods: This quasi-experimental study was conducted on 200 pregnant women (100 women in the intervention and 100 in the control groups) referred to health centers for prenatal care in 2019. They were selected by the block randomization sampling method. The control group received the routine care and the intervention group, in addition to routine care, attended a 90-min long consultation session based on SDM. The women were contacted via phone at 14 weeks of pregnancy to collect data on their undertaking prenatal screening tests. The demographic characteristics form and O'Conner's decisional conflict scale were filled out immediately after the consultation session for the intervention group. The obtained data were analyzed by the Chi-square, Fisher exact-test, Mann-Whitney U, and linear regression tests. The P value less than 0.05 was considered statistically significant.

Results: There was no significant difference between the two groups regarding women's demographic characteristics, except for education level, job, and insurance coverage. The Mean±SD DC score was significantly lower in the intervention group (7.35±8.55) compared to the control group (27.32±13.81) (95%CI; 16.80-24.19, P=0.001). In addition, there was a significant difference between the two groups in terms of undergoing the offered FTS (P=0.04). The DC scores ≥25 were associated with a decreased chance of undergoing FTS (P=0.02). Women were less likely to undergo FTS when they were self-employed (OR=0.15, 95%CI; 0.03-0.71, P=0.01).

Conclusion: The SDM consultation can help women experience significantly lower levels of DC. Furthermore, factors such as self-employment can prevent women from undergoing FTS despite lower levels of DC.

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Highlights

- Pregnant women are uncertain about undergoing first trimester screening tests.
- The shared decision-making focuses not only on the exchange of information but also on the values and preferences of women.
- The shared decision-making consultation can help women experience significantly lower levels of decisional conflict.

Plain Language Summary

Decisional Conflict (DC) among women at the time of recommendation for First Trimester Screening (FTS) tests is high, making it difficult to decide whether to take them. The decision-making process on FTS is a complex task influenced not only by providing women with adequate information but also by other factors (e.g., cost of FTS, emotional factors, values). Shared Decision-Making (SDM), with its collaborative and deliberative nature, allows consultants to incorporate accurate information and evidence-based information on short- and long-term outcomes of each option (undertaking or not undertaking the offered FTS). This finding indicated that the SDM approach could help women to elicit their values, personal circumstances, and specific socio-cultural context live on it. Therefore, women can decide depending on their individual values and preferences and experience lower DC. Furthermore, women are uncertain not only because of the inherent difficulty of the complex decision they are confronting but also because of modifiable factors (e.g., economic constraints). In societies such as Iran, that FTS is not covered by insurance and is self-funded by families, the additional charged fee for FTS is a financial burden and can hinder women from undergoing FTS.

Introduction

The guideline of the prenatal aneuploidy screening program in the first trimester of pregnancy was introduced in 2011 by the Ministry of Health and Medical Education of Iran [1]. All health care providers (without receiving medical genetic counseling training) were requested to offer the First Trimester Screening (FTS) tests to all pregnant women who attended clinics in the first trimester, regardless of women's age, as part of their routine pregnancy care program [2]. A previous study showed that the decision-making process on FTS is a complex task. It is influenced not only by providing women with adequate pretest information about FTS [3] but also by various other factors, such as attitude toward test (accuracy, safety), cost of FTS, demographic characteristic, emotional factors, and different hopes or dreams for the unborn baby [4-6].

A study in Iran showed that Decisional Conflict (DC) among women at the time of FTS recommendation is high, making it difficult to decide whether to perform the tests [3]. In addition, it is difficult for laypeople to interpret the test results because of their scientific nature and inherent complexities [7]. These factors are associated with the ambivalence of women toward undergoing screening tests. Hartwig reported that 13% of women at increased risk for FTS have a high level of DC [8], which can lead to decisional delay and loss of opportunity to use legal abortion before the 19 weeks of pregnancy or decline of FTS [9, 10].

All of the evidence, as mentioned above, clarifies that a consultative approach rather than a mere exchange of information is required to focus on women's concerns to provide medical, technical information and supports [11]. Shared decision-making (SDM) (as a patient-centered approach to counseling) with its collaborative and deliberative nature engages women/couples in the decision-making process. It allows consultants to incorporate accurate information (e.g., diagnosis, course of illness) and evidence-based information on short- and long-term outcomes of each option (undertaking or not undertaking the offered FTS) and to clarify what is most important to the subjects [12-14]. Therefore, women/couples can decide depending on their individual values and preferences.

A recent review of the literature on this topic showed that only one study [15] examined how much shared decision-making SDM can affect DC and uptake of FTS among pregnant women in low- to middle-income countries with diverse cultural, religious, financial, and health service context. Therefore, this study investigates

the effect of SDM about undergoing FTS on decisional conflict immediately after consultation and uptake of FTS by the end of the first trimester of pregnancy.

Materials and Methods

The current quasi-experimental study was conducted on 200 women (100 women in the intervention and 100 in the control groups) referred to governmental health centers for prenatal care in Zahedan, Iran, from April to September 2019.

The sample size was calculated to be 79 pregnant women for each group considering α=0.05, β=0.20, $z_{1-\alpha/2}$=1.96, $z_{1-\beta}$=1.28, and μ_1=37.46, μ_0=31.21, S_1=16.94, S_2=10.39 for mean Decisional Conflict Scale (DCS) scores reported by Kordi and associates [3]. Considering possible loss to follow-up (about 25%), a total of 105 pregnant women were considered for each group. The participants included pregnant women with a gestational age of fewer than 13 weeks. The inclusion criteria were aged 18 years or older, a singleton pregnancy, no previous history of a disabled child or pregnancy with fetal malformation, lack of history of mental illness/psychiatric antecedents or illicit drug use (based on electronic records), pregnancy not happened after infertility, and ability to speak and understand Persian. Women who were the prior candidate of amniocentesis/chorionic villus sampling (e.g., carrier of beta-thalassemia major) or their fetus diagnosed with sonography abnormalities were not included in the study.

Multistage sampling was used for data collection. At first, Zahedan City was divided into three areas based on socioeconomic conditions (according to the expert opinion of the District Health Network of Zahedan). Then, considering the total number of "comprehensive health services centers" and pregnant women with gestational age<13 weeks in each stratum, nine health centers in the northern area, six in the central, and nine in the southern area of the city were randomly selected using a list of all the health centers in each area of the city. At each health center, the name and addresses of all women with a pregnancy of fewer than 13 weeks were identified through the electronic medical record system. All information on households and types of health care provided for pregnant women at urban health posts/or health centers were recorded in the above-mentioned system. The second researcher contacted the subjects (n=279) via phone calls, inviting them to participate in a counseling session. In this stage, 69 women were excluded from the study (Figure 1). In the present study, four blocks were used to allocate participants equally to each group. At first, all the six possible balanced combinations of assignment within the block were calculated, and blocks were randomly selected using a random number table. Then, the number of participants was placed in opaque envelopes. To solve the problem of predicting subsequent assignments, another person who was not involved in the study did all of these steps.

The research tools included a demographic information form and an O'Conner's DCS questionnaire. Age, educational level, job, insurance coverage, gravida, history of stillbirth (as the primary demographic characteristics of women), age, education level, and job (as the primary demographic characteristics of men) were collected. O'Conner's decisional conflict scale is a validated 16-item self-report questionnaire. It measures uncertainty in choosing options [16, 17]. The DCS consists of 5 subscales labeled as uncertainty (3 items), informed (3 items), values clarity (3 items), support (3 items), and effective decision subscale (4 items). The participants responded to each item using a 5-point Likert scale ranging from 0 (strongly agree) to 4 (strongly disagree).

The total scale score was obtained by summing up across all the items, divided by 16 and multiplied by 25; the total score ranged from 0 to 100. The same steps were performed for each subscale. For example, for the uncertainty subscale, the total scale score was obtained by summing up across all the items, divided by 3 (items in this subscale), and multiplied by 25; the total score ranged from 0 to 100. Higher scores on the scale or subscales showed higher DC, uncertainty, and less effective choice. It was stated that "scores lower than 25 are associated with implementing decisions, while scores exceeding from 37.5 are associated with decision delay or feeling unsure about implementation" [17, 18]. This scale has already been used in Iran [19, 20]. In the present study, the Cronbach α for the total scale was measured at 0.94, and for the subscales, including uncertainty, informed, values clarity, and support was calculated as 0.8, 0.89, 0.9, and 0.7, respectively.

Furthermore, all women (n=210) were contacted via telephone at 14 weeks of pregnancy (when the opportunity for FTS tests was over) to collect data on undertaking combined FTS tests. Therefore, all participants were asked if they had undergone FTS tests. Participants were also asked to take a photo of the test results and sonography report and send them to the second researcher (on social media). In addition, the results of the first follow-up showed that 10 women had a spontaneous abortion before 13 weeks (five in each group). Women (n=210) were contacted via telephone at 20 weeks of

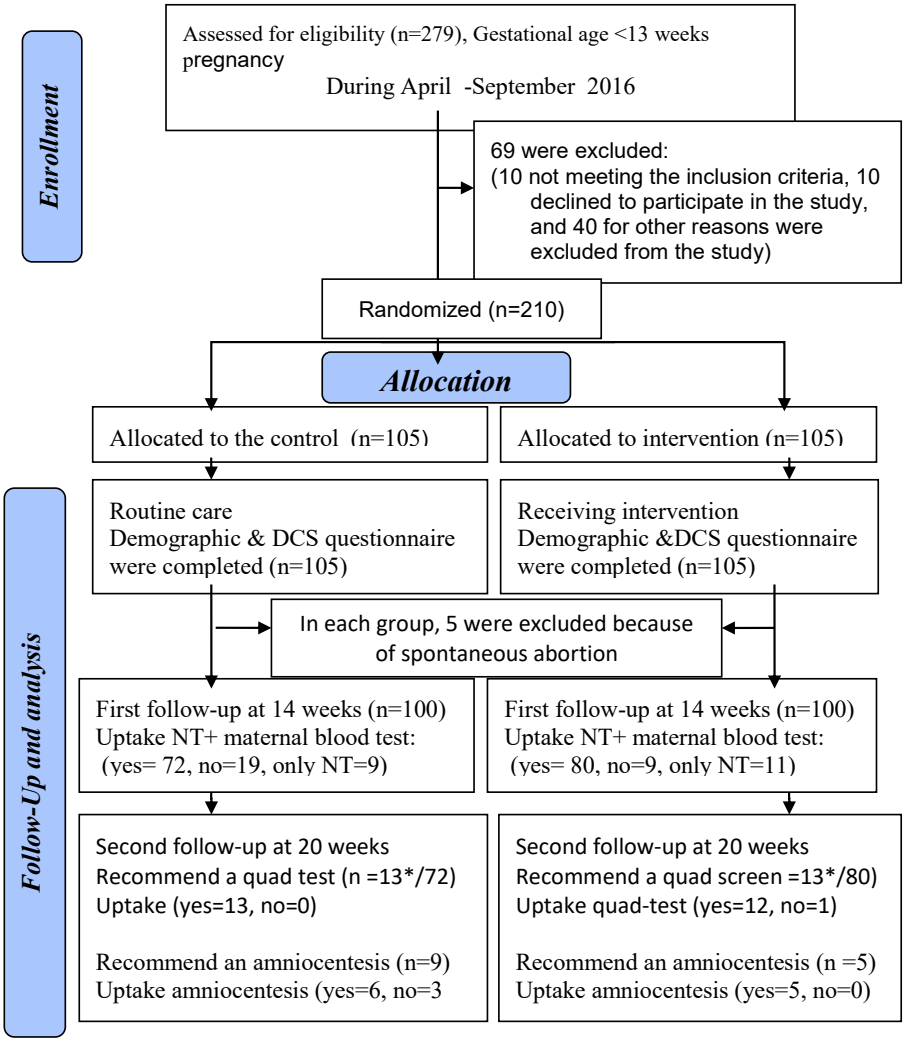

Figure 1. Consort flow diagram of study participants

* Women with intermediate risk.

pregnancy (when the opportunity for a quad test and amniocentesis was over) to collect data on undertaking required further testing to confirm the diagnosis.

The intervention group participated in a 90-min long counseling session based on stages of the three-talk model of SDM (choice talk, options talk, decision talk) before the 13th week of pregnancy (Table 1). The content of the consultation session was based on the latest "the national guidelines for the prevention of fetal chromosomal abnormalities in Iran" developed by the Ministry of Health, Treatment, and Medical Education of Iran [1]. The individual counseling session was held in the presence of women (and sometimes one of their relatives) and the counselor in a separate room other than the maternal and child health service room. The counselor was a postgraduate counseling student trained on SDM. The initial counseling sessions (n=5) were held. Moreover, 35 more sessions (out of 100 counseling sessions) were audiotaped, transcribed, and checked for essential and ideal elements of SDM and general qualities of consultation.

At the end of the session, pamphlets containing the session's content were given to all participants. The demographic characteristics form and Decisional Conflict Scale (DCS) were filled out immediately after the consultation session.

The collected data were analyzed in SPSS, version 21.0 (IBM SPSS Statistics for Windows, Armonk, NY: IBM. Corp). The two-tailed tests were employed to compare variables between the intervention and control groups. The P value of less than 0.05 was considered statistically significant. The Kolmogorov-Smirnov test was applied to measure the normality of continuous

Table 1. Essential elements and contents of shared decision making counseling sessions

Stages of the Three-Talk Model of SDM	Essential Elements	Contents
Choice talk	Explain the problem	Every pregnant woman has a chance of carrying a baby with a chromosomal anomaly.
	Present options	It is time to think about whether to undergo a prenatal screening test or not.
Option talk	Elicit couples' knowledge about prenatal screening tests	They were asked to express their knowledge of prenatal screening tests and try to understand their practical knowledge as expressed in their narratives. Note: Check information and clarify their understanding and misconceptions
Decision talk	Elicit and discuss pros/cons about benefits/risks/costs for child and family (in short- and long-term)	Use of participants' explanations and narratives to extract: 1. the physical, psychological, financial, and social impact of an affected baby on her/his family in this particular context 2. Identify the reasons for their uncertainty about undergoing of prenatal screening test Note:Check information and clarify understanding, whether they are correct and what their misconceptions are.
	Elicit couples' values/preferences	Use of participants' explanations and narratives to extract what matters the most to them. Note:List their most important values and concerns.
	Ask about their decisions	They were asked: are you ready to decide? /do you need more time? Note:Sometimes they explicitly postpone the test. A consultant checked their reasons.
	Discuss patient's abilities	They were asked: how confident are you that you can make your decision? Note:Sometimes they asked about how to make a prescription for the test with a stamp of an obstetrician.
	Arrange follow-up to track the outcome	Telephone follow-up at 14 and 20 weeks of gestational age to track the outcome of their decision

data. When the data were not normally distributed, a Mann-Whitney U test was performed. The Chi-square and Fisher exact-tests were performed to compare categorical and binary data between the two groups.The linear regression model was used to estimate the association between the DC score (dependent variable) and the intervention program for controlling factors of age, job, and education level of husbands, as well as insurance coverage, job, and education level of the pregnant women. Finally, the logistic regression model was used to estimate the association between uptake of FTS (0=No, 1=Yes) and independent variables (i.e., women's job, DC score, education level of women, insurance coverage, husband's job, and their education level). Based on a previous study by Vlemmix, the decisional scale score was converted into a categorical variable (DCS<25, 25≤DCS≤37.5, DCS>37.5) [21]. All independent variables were considered categorical. The P value of 0.05 was chosen for allowing a variable to enter the model and also to retain independent variables in the model. We adopted the forward likelihood ratio (LR(method in logistic regression to study the role of each independent variable in uptaking FTS. The overall goodness of fit model was tested using the Hosmer-Lemeshow test.

Results

There were no significant differences between study groups in terms of religion. The rest of the demographic characteristics of the pregnant women who participated in the study are shown in Table 2. The findings indicate that women's education (P=0.001), job (P=0.003), and insurance coverage (P=0.008) were significantly different between groups.

There were significant differences (P=0.02) between the two groups husband's Mean±SD age (33.12±5.58 and 31.26±5.83 years in the intervention and control groups, respectively), husband's education level (P=0.001), and husband's job (P=0.001). The result showed that most men had a diploma to university education in the intervention (83%) and control groups (64%). In addition, 17% of men in the intervention and 36% of men in the control groups had primary to secondary education. Most men were "self-employed (with fixed salary per month)" or were organizational employees in the intervention (94%) and control group (77%).

The collected data showed that the total DC score was significantly lower in the intervention group compared to the control group (P=0.001) (Table 3). The multiple linear regression model indicated comparable results

Table 2. Comparison of participant's demographic characteristics between groups (n=100 in each group)

Women's Characteristics		No. (%)		P
		Intervention	Control	
Age (y)	18-25	29(29)	39(39)	0.43*
	26-30	30(30)	26(26)	
	31-35	20(20)	20(20)	
	≥36	21(21)	15(15)	
Gravida	1	25(25)	33(33)	0.34*
	2	27(27)	20(20)	
	≥3	48(48)	47(47)	
Number of abortions	0	73(73)	78(78)	0.69*
	1	20(20)	17(17)	
	≥2	7(7)	5(5)	
Stillbirth	Yes	4(4)	1(1)	0.2**
	No	96(96)	99(99)	
Women's education level	Illiterate and primary school	100	27(27)	0.001*
	Secondary school	6(6)	16(16)	
	Diploma	37(37)	32(32)	
	University degree	47(47)	25(25)	
Women's job	Housewife	74(74)	92(92)	0.003*
	Self-employed	11(11)	3(3)	
	Organizational employee	15(15)	5(5)	
Insurance coverage	Public-governmental	73(73)	90(90)	0.008*
	Private health	19(19)	7(7)	
	None	8(8)	3(3)	

* Chi-square test; ** Fisher exact-test

examining the DC scores between groups after controlling such variables as age, job, and education level of men, as well as insurance coverage, job, and education level of women.

In addition, data showed that women's jobs and DC scores were significant factors in the uptake of FTS. The overall goodness of fit model tests for the Hosmer-Lemeshow test (χ^2=0.66, df=4, Sig.=0.95) was good. Accord-

Table 3. Comparison of decisional conflict between groups (n=100 in each group)

Decisional Conflict Score	Mean±SD		P (Univariate)	P* (Multivariate)	β	95% CI	
	Intervention	Control				Lower	upper
Total score	7.35±8.55	27.32±13.81	0.001	0.001	12.51	16.80	24.19
Uncertainty	9.41±12.90	25.41±15.55	0.001	0.001	15.55	12.65	21.57
Informed	5.83±9.05	30.83±19.08	0.001	0.001	24.93	21.67	30.93
Values clarity	6.66±10.66	29.50±18.89	0.001	0.001	22.31	19.57	29.07
Support	9.58±12.99	28.25±17.84	0.001	0.001	18.94	13.60	23.47
Effective decision	7.75±12.32	30.33±18.71	0.001	0.001	22.51	17.56	27.58

* After adjustment for age, job, and education level of men, as well as insurance coverage, job, and education level of women by multiple linear regression.

Table 4. Final logistic regression model of factors associated with actual uptake of prenatal screening tests

Variables		B	SE	P	OR	95%CI	
						Lower	Upper
Women's jobs Housewife (Reference)	Self-employed (with fixed salary per month)	-1.83	0.76	0.01	0.15	0.03	0.71
	Organizational employee	1.10	1.12	0.32	3.03	0.33	27.29
Decisional conflict score <25 (Reference)	25-37.5	-1.15	0.52	0.02	0.31	0.11	0.89
	>37.5	-2.49	0.60	0.001	0.08	0.02	0.27

ing to the obtained results, DC scores≥25 were associated with a decreased chance of undergoing prenatal tests (OR=0.31; 95%CI; 0.11-0.89; P=0.02). The logistic regression model showed that women's education level, insurance coverage, age, job, and education level of the husbands did not contribute significantly to the uptake of FTS (Table 4).

Eleven women in the intervention group (11/100) and nine (9/100) women in the control group merely had undergone first-trimester nuchal translucency thickness measurement. The reasons for not undergoing the combined test were as follows: the physician did not order the combined test (15/20, 75%), high-stress level of women (3/20, 15%), and cost of the test (2/20, 10%). Accordingly, because standard guidelines were not followed, these women were excluded from the present study. Nine women (9/89, 10.11%) in the intervention group and 19 women (19/91, 20.88%) in the control group declined to undergo combined FTS. The Chi-square test showed a statistically significant difference between groups regarding undertaking or not undertaking the offered FTS (P=0.04).

Discussion

The present study was conducted to examine the effect of the SDM counseling program on decisional conflict and undertaking combined FTS. In line with a previous study [21], the present study results showed that SDM in genetic counseling could significantly reduce DC. Although Kordi's study showed that the two methods of group and face to face education are also effective in increasing information and reducing DC in pregnant women about FTS, the mean score of DC in the present study after counseling was much lower than their study for face to face education method, and for group education method [3]. In the SDM sessions, women were encouraged to tell their narratives (e.g., about FTS and families/or neighbors who have children with Down syndrome). This method helped the mutual exchange of information, and provided clear information to increase women's knowledge about available options. Therefore, the SDM approach allows not only to improve women's knowledge but also to improve their understanding of FTS [22, 23].

Another possible explanation for the decrease in the mean score of DC is related to the value subscale in the DCS. Women who participated in an SDM approach feel more clear about personal values (e.g., fetal life, having healthy children), which were more important to them. Previous studies showed that "values inform our views of how things should be and guide us when difficult choices need to be made", and they are fundamental in the clinical decision-making process [24, 25]. As in the previous study, data from interviews with women during the counseling session showed that religious beliefs (e.g., the unacceptability of abortion and reliance on faith) could lower FTS uptake [26]. In such a complex situation, the SDM approach can help women to elicit their values, personal circumstances, and specific socio-cultural context live on it. SDM, with its collaborative process, encouraged women to weigh the risks and benefits of each option and talk about their opinions and preferences. Finally, it helped women choose alternatives, including risk, regret, or challenge to their life values [2, 14, 27]. Furthermore, previous studies showed that women are uncertain not only because of the inherent difficulty of the complex decision they are confronting but also because of modifiable factors such as economic constraints [28, 29]. The logistic regression model confirms earlier findings that women with lower income (e.g., self-employed women) were less likely to uptake FTS. This finding indicated that in societies, such as Iran, that FTS is not covered by insurance, the additional charged fee for FTS is a financial burden and can hinder women from undergoing FTS [30].

In summary, the collected data showed that women who participated in an SDM session experienced low levels of DC immediately after the counseling session. In contexts, such as Iran, that FTS was viewed as routine care, a counseling session (e.g., SDM) should be considered to help informed decision-making among women/couples about undertaking or not undertaking the screening tests. Besides, the present study showed that uptake of FTS is also contextualized within the women's socioeconomic status. Thereby, financial constrain can prevent women (e.g., self-employed women) from undergoing screening tests despite their desire.

Some limitations should be considered when interpreting the results of the present study. Firstly, this study was conducted in a specific socioeconomic context in the southeast of Iran; therefore, the results might not be generalizable to the national level. Secondly, Further research is needed to investigate women and or family members' willingness to pay for FTS. Finally, in the present study, we could not link SDM counseling approaches to the high-risk and intermediate groups offered invasive prenatal testing or second-trimester tests. Therefore, further investigation is also needed to evaluate the association between the variables mentioned above.

Ethical Considerations

Compliance with ethical guidelines

The present study was approved by the Ethics Committee of Zahedan University of Medical Sciences, Zahedan, Iran (March 22, 2019); (Code: IR.ZAUMS.REC.2018.490). Moreover, the required permissions were obtained from the Zahedan Deputy of Health and directors of all healthcare facilities. All participants signed the informed consent form.

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Author's contributions

Conceptualization: Zahra Moudi, Raheleh Jam, and Mostafa Montazer Zohour; Writing the original draft: Zahra Moudi, Raheleh Jam, Hossein Ansari, and Mostafa Montazer Zohour; Data collection: Zahra Moudi and Raheleh Jam; Data analysis: Zahra Moudi, Raheleh Jam, and Hossein Ansari; Approval of the final version: All authors.

Conflict of interest

The authors declared no conflict of interest.

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