

Clinical Research

Is Family Support A Factor in Patient Adherence to Immunosuppressive Treatment? A Descriptive Study

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ABSTRACT

Objective: Non-adherence to immunosuppressive treatment can cause graft rejection in kidney transplantation patients. The reasons for non-adherence have been shown to be side-effects of the drugs, compliance fear, and lack of family support. The aim of this study was to determine the effect of family support on drug adherence.

Material and Method: This study was conducted on 98 patients followed up in the polyclinic of a public hospital following kidney transplantation. The data were obtained from a patient information form, the Perception of Family Support Scale (PSS-Fa), the Immunosuppressive Treatment Adherence Scale (ITAS), and the tacrolimus blood plasma level of the patients.

Results: In patients aged ≤ 40 years, the PSS-Fa was determined to be high ($p < 0.05$), and family support was determined to have no effect on time since transplantation, donor type and rejection attack ($p > 0.05$). The mean ITAS points were 11.03 ± 0.90 and the tacrolimus blood plasma level mean standard deviation was < 2.47 , indicating high drug adherence. A positive correlation was determined between age and ITAS points ($p < 0.05$). No correlation was determined between the tacrolimus blood plasma level standard deviation mean value and the ITAS and PSS-Fa mean points ($p > 0.05$).

Conclusion: No relationship was determined between family support and drug adherence. Further studies can be recommended to evaluate groups including different transplantation types to investigate the effect of family support on drug adherence.

Keywords: Kidney Transplantation, Immunosuppressive Treatment, Family Support, Nursing.

ÖZ

Hastaların İmmünoşüpresif Tedaviye Uyumunda Aile Desteği Etkili Bir Faktör Mü? Tanımlayıcı Bir Çalışma

Amaç: Böbrek transplantasyonu yapılan hastalarda immünoşüpresif tedaviye uyumsuzluk greft reddine neden olabilir. Uyumsuzluk nedenlerinin ilaçların yan etkileri, uyum korkusu ve aile desteğinin olmaması olduğu gösterilmiştir. Bu çalışmanın amacı, aile desteğinin ilaç uyumuna etkisini belirlemektir.

Gereç ve Yöntem: Bu çalışma bir devlet hastanesinin polikliniğinde böbrek nakli sonrası takip edilen 98 hasta üzerinde yapıldı. Veriler hasta bilgi formu, Aile Destek Algısı Ölçeği (PSS-Fa), İmmünoşüpresif Tedaviye Uyum Ölçeği (ITAS) ve hastaların takrolimus kan plazma düzeylerinden elde edildi.

Bulgular: Kırk yaş ve altı hastalarda PSS-Fa'nın yüksek olduğu ($p < 0.05$), aile desteğinin transplantasyondan bu yana geçen süre, donör tipi ve red atağı üzerinde etkisinin olmadığı belirlendi ($p > 0.05$). Ortalama ITAS puanları 11.03 ± 0.90 ve takrolimus kan plazma düzeyi ortalama standart sapması < 2.47 idi, bu da ilaca yüksek uyumu gösterir. Yaş ile ITAS puanları arasında pozitif korelasyon saptandı ($p < 0.05$). Takrolimus kan plazma düzeyi standart sapma ortalama değeri ile ITAS ve PSS-Fa ortalama puanları arasında korelasyon saptanmadı ($p > 0.05$).

Sonuç: Aile desteği ile ilaç uyumu arasında ilişki saptanmamıştır. Aile desteğinin ilaç uyumuna etkisini araştırmak için farklı transplantasyon tiplerini içeren hasta gruplarını değerlendirmek için ileri çalışmalar önerilebilir.

Anahtar Sözcükler: Böbrek Nakli, İmmünoşüpresif Tedavi, Aile Desteği, Hemşirelik.

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Treatment compliance in kidney transplantation patients is complex and multifactorial. Following transplantation, patients have to take multiple drug treatments, which may have significant side-effects, and require constant monitoring and frequent dose changes (1). Non-adherence to the treatment increases the

risk of graft loss and death, and increases the medical costs (2). Therefore, following transplantation, patients must take drugs daily and attend polyclinic appointments regularly (3). The appropriate follow up of a patient following transplantation increases graft survival and improves quality of life (4).

After transplantation, patients can experience intense

stress because of hospitalisations, frequent appointments, intense medical treatment, concerns about rejection, returning to work, and impaired family dynamics (5, 6). The intense stress experienced, a young age, and a longer time since the transplantation can cause increased non-adherence to drugs (7). It has been reported that there could be treatment non-adherence in approximately one-third of transplantation patients and 36% of kidney allograft losses are due to drug non-adherence (6). In a study by Williams et al., (8) patients reported that they forgot to take the drugs because they were using multiple drugs, the drugs interfered with their lifestyle, or they were busy with work or social life.

Adequate social support has a positive effect on the development and protection of health and on the treatment and rehabilitation of diseases. It also increases patient compliance to the disease process (9). Characteristics of the family environment, and the quality of social support at home are factors which affect drug adherence (10). A lack of family and social support leads to adherence problems and negativities in treatment (9). The attitude of family members during the disease process affects the patient psychologically either positively or negatively, and a lack of social support and negativity experienced by the patient in daily life cause feelings of hopelessness (11-13). The ability of the patient to manage the disease is based on the competency for personal care required and the behaviour of the family. Family support increases the motivation of the individual, ensures that information and feedback is obtained, and thus may change the self-care behaviour of the patient (14). Xiaolian et al. (15) determined a positive relationship between family support and self-care behaviour. In another study investigating psychosocial factors in drug adherence, Killian et al. (10) showed that family conflict and poor communication in the family were among the factors causing non-adherence of patients to treatment.

Nurses have an important function in preventing graft losses, improving life after transplantation, and increasing adherence to drug treatment. Clinical screening of risk groups and person-specific interventions to improve adherence have to be developed (2). The development of family support, self-sufficiency, and self-care behaviours form an important part of nursing practice, and interventions are required in nursing leadership to be able to improve adherence. To understand the routines of patients, nurses must work in collaboration with them to provide solutions to increase adherence (8). Therefore, there is a need for more information about the psychosocial factors related to the high rate of non-adherence for nurses to be able to develop psychosocial interventions and apply them to patients at risk. It is thought that determination of the perceived family support of patients after transplantation will be able to increase drug adherence and will provide a significant contribution to the provision of psychological support. Family support means that the perceived needs of an individual for emotional, moral, and close support are

met in addition to the need for information and feedback (15). The acceptance of the disease and adherence to treatment of patients can be increased with perceived support from the family. By investigating family support systems, nurses can keep patients with a need for support under close follow up, and by enabling participation of the family in the treatment process can help to reveal other factors which may cause forgetfulness or non-adherence. Thus, adherence of the patient to treatment can be achieved, graft survival and quality of life can be improved, and medical costs can be reduced.

No study could be found in literature that has investigated the effect of family support on adherence to immunosuppressive treatment in adult transplantation patients. Therefore, the aim of this study was to determine the effect of perceived family support on drug adherence following kidney transplantation. To achieve this, answers were sought to the following questions:

1. What is the level of drug adherence of the patients?
2. What is the level of family support of the patients?
3. Does family support affect drug adherence?

MATERIAL AND METHOD

Research Type

This was a descriptive, cross-sectional study, conducted to determine relationships between variables.

Place and Date of Research

A total of 120 patients followed up in the transplantation polyclinic of a public hospital between 01 February and 31 April 2021 were initially enrolled in the study.

Study Universe and Sample

The study universe comprised 120 patients followed up in the nephrology polyclinic of a public hospital between 01 February and 31 April 2021. In accordance with information in the study by Madran et al. (16), G*power analysis was applied, effect size was calculated as $d=0.7491456$, α err prob= 0.05, power (1- β err) prob= 0.90, and the sample size was calculated as 82 subjects. It was aimed to reach 120 patients followed up in the polyclinic. After the exclusion of 10 patients with communication problems and 12 patients who did not wish to participate, the study was completed with 98 patients.

Study inclusion criteria;

- Voluntary participation in the study,
- Age ≥ 18 years,
- To be able to evaluate adherence to immunosuppressive treatment, a period of at least 3 months since hospital discharge after the transplantation operation (16),
- Using tacrolimus immunosuppressive drugs,
- Able to take the immunosuppressive drugs independently,

- No mental disability or problem of perception,
- No communication difficulties.

The patients, who had problems communicating, wanted to voluntarily leave the study, and did not complete it three months after the transplant, was excluded from the study.

Data Collection Tools

In accordance with literature, the following forms were used; a specially prepared patient information form, the tacrolimus blood plasma level standard deviation mean value for the biological evaluation of drug adherence, the Immunosuppressive Treatment Adherence Scale (ITAS) for the self-reporting of drug adherence, and the Perception of Family Support Scale (PSS-Fa). The data were collected by the researcher in face-to-face interviews with the patients waiting for polyclinic examination.

There is no method to measure drug adherence which does not have a disadvantage and no method has been shown to be superior to any other. Therefore, it has been recommended that at least two methods are used to evaluate drug adherence (17). In the current study, two different methods were used, one biological and one based on self-reporting.

Patient Information Form

The patient information form including descriptive characteristics of the patients was prepared by the researcher in accordance with literature (16,18). The form included descriptive characteristics such as age, gender, marital status, education level, occupation, and income level.

Biological Evaluation of Drug Adherence

Patzer et al., (6) stated that at least one low level of drugs from 5 routine checks was evaluated as drug non-adherence. In the evaluation, only the the tacrolimus level was taken as the base. In the centre where this study was conducted, patients use tacrolimus at 12-hour intervals, and the drug level was evaluated by examining the blood plasma level at 12 hours after drug intake.

In the biological evaluation, the retrospective result of 5 drug level measurements taken over a period in the range of 7 months to 2.5 years was taken for evaluation of the patients using tacrolimus. The standard deviation value was calculated of the tacrolimus levels of each patient. Patients with tacrolimus blood plasma level standard deviation mean value of >2.48 were evaluated as not adherent to immunosuppressive treatment, and those with a value <2.47 as adherent (18).

Immunosuppressive Treatment Adherence Scale (ITAS)

The ITAS was developed by Chisholm et al. (19) in the USA in 2004 for the evaluation of immunosuppressive treatment adherence (ITA) of patients after organ transplantation. Validity and reliability studies of the scale in Turkish were conducted by Bayhan in 2016 and the Cronbach alpha reliability coefficient was found to be $=0.65$ ($n=50$) (16). The ITAS questions the

ITA within the last 3 months of patients after organ transplantation. It has 4 items, with 4-point Likert -type responses.

Scoring of the ITA items is made with 3 points corresponding to 0% response, 2 points for a 0-20% response, 1 point for 21-50% response, and 0 points for $>50\%$ response. Total points of the scale range from 0-12, with higher points showing higher adherence. To be able to calculate adherence, calculations are made with the correct proportion according to the responses given by the patients, the options appropriate to the result are marked, and the total points obtained by the patient from the scale are calculated (16). Several studies in literature have used this scale (18, 20-22).

The Perceived Family Support Scale (PSS-Fa)

This scale was developed by Procidano ME and Heller K (1983), and adapted to Turkish by Sorias (1992). The 20-item PSS-Fa was found to be valid and reliable for the Turkish population with validity and reliability studies by Prof. Dr. Mehmet Eskin (1993)(23). The 20 items of the scale are scored according to the responses of "yes", "no", or "partially". For items 3, 4, 16, 19, and 20, the points are given as no=2, yes=0, and partially=1, and the reverse is applied to all the other items as no=0, yes=2, and partially=1. The total points range from 0-40, with higher points indicating good family support (23). The Cronbach alpha value for the scale was calculated as 0.949 in this study. This scale has been used in other studies in literature (14),(24),(13).

Ethical Aspects of the Study

Approval for the study was granted by the Non-Interventional Clinical Research Ethics Committee of KSU Medical Faculty (decision no: 03/18.01.2021), and permission was obtained from the hospital administration. All the study subjects provided signed, informed consent for participation in the research.

Statistical Analysis

Data obtained in the study were analyzed statistically using SPSS vn. 23.0 software. Descriptive data were analyzed using mean \pm standard deviation values, number (n) and percentage (%). Conformity of the data to normal distribution was examined with the skewness-kurtosis coefficient, and coefficients in the range of -2 to +2 showed normal distribution of the data (25). In the comparisons of two groups of data with normal distribution, the Independent Samples t-test was applied, and for data not showing normal distribution, the Mann Whitney U-test. Correlations between the tacrolimus plasma level standard deviation mean value, ITAS and PSS-Fa points, and age were evaluated with Pearson correlation analysis.

RESULTS

Evaluation was made of a total of 98 patients, comprising 61 (62.2%) males and 37 (37.8%) females with a mean age 42.47 ± 12.87 years (range, 18-72 years), and 56.1% of the patients were ≥ 41 years. Other demog-

raphic features were determined as education level of primary school in 53 (54.1%) patients, 37 (48%) patients were employed, income was reported to be lower than outgoings by 57 (58.2%), and 70 (71.4%) patients had healthcare insurance (Table 1).

The time since transplantation was ≥ 6 years in 57 (58.2%) cases, the transplantation was from a live donor in 59 (60.2%) cases, of which 18 (18%) were from the mother of the patient. No rejection attack had been experienced by 77 (78.6%) patients (Table 1).

The standard deviation value of the last five tacrolimus drug level measurements of each patient was examined and the mean drug level standard deviation value was found to be 1.97 ± 1.30 (range, 0.00-6.95). Of the patients using immunosuppressive treatment containing tacrolimus, 71 (72.4%) with a mean tacrolimus plasma level standard deviation value of < 2.47 were evaluated as adherent to treatment, and 27 (27.6%) with standard deviation value of > 2.48 were evaluated as non-adherent (Table 1).

Table 1. Sociodemographic and clinical characteristics of the kidney transplantation recipients (n =98).

Characteristics	n	%	
Age	≤ 40 years	43	43.9
	≥ 41 years	55	56.1
Gender	Female	37	37.8
	Male	61	62.2
Marital status	Married	70	71.4
	Single	28	28.6
Education level	Primary school	53	54.1
	Middle school	45	45.9
Employment status	Employed	37	48.0
	Unemployed	29	29.6
	Retired	22	22.4
Income level	Income equal to outgoings	41	41.8
	Income less than outgoings	57	58.2
Health insurance	Yes	70	71.4
	No	28	28.6
Time since transplantation	≤ 5 years	41	41.8
	≥ 6 years	57	58.2
Donor type	Living donor	59	60.2
	Cadaver donor	39	39.8
Relationship status of live donor*	Mother	18	18.4
	Father	15	15.3
	Brother or sister	9	9.2
	Wife or husband	17	17.3
Experience of rejection attack	Yes	21	21.4
	No	77	78.6
Tacrolimus blood plasma level standard mean	< 2.47	71	72.4
	> 2.48	27	27.6

*calculated as n =59.

The results of the comparisons of the mean standard deviation values of tacrolimus blood plasma level with the mean ITAS and PSS-Fa points are shown in table 2. No statistically significant difference was determined in the mean standard deviation values of tacrolimus blood plasma level according to patient age ($p > 0.05$). The ITAS points were determined to be significantly low ($p = 0.010$) and the PSS-Fa points were significantly high ($p = 0.01$) in the patient group aged ≤ 40 years compared to the older group. No statistically significant difference was determined between the ITAS and PSS-Fa total points in respect of gender, education level, time since transplantation, donor type, rejection attack status, and the mean standard deviation value of tacrolimus blood plasma level ($p > 0.05$) (Table 2).

Table 2. Comparisons of some patient characteristics, drug adherence, and PSS-Fa points.

Characteristics	Tacrolimus blood plasma level standard mean			ITAS		PSS-Fa	
		M \pm SD	Test / p	M \pm SD	Test / p	M \pm SD	Test / p
Age	≤ 40 years	1.30 \pm 0.46	1.056/0.604	10.76 \pm 0.97	0.684/0.010	30.51 \pm 8.30	7.98/0.01
	≥ 41 years	1.25 \pm 0.43		11.23 \pm 0.79		25.25 \pm 11.76	
Gender	Female	1.24 \pm 0.43	1.290/0.582	10.91 \pm 0.98	0.00 \pm 0.342	30.13 \pm 10.08	0.368/0.063
	Male	1.29 \pm 0.45		11.09 \pm 0.85		26.00 \pm 10.79	
Education level	Primary school	1.24 \pm 0.43	2.032/0.472	11.05 \pm 0.94	0.610/0.759	27.47 \pm 10.28	0.509/0.929
	Middle school	1.31 \pm 0.46		11.00 \pm 0.85		27.66 \pm 11.22	
Time since transplantation	≤ 5 years	1.29 \pm 0.46	0.400/0.750	11.07 \pm 0.95	1.196/0.694	26.92 \pm 10.70	0.019/0.620
	≥ 6 years	1.26 \pm 0.44		11.00 \pm 0.86		28.01 \pm 10.71	
Donor type	Living donor	1.25 \pm 0.43	1.258/0.567	11.00 \pm 0.94	-0.70/0.787*	27.81 \pm 10.02	1.522/0.775
	Cadaver donor	1.30 \pm 0.46		11.07 \pm 0.83		27.17 \pm 11.69	
Rejection attack	Yes	1.38 \pm 0.49	4.002/0.227	10.80 \pm 1.03	1.013/0.207	28.95 \pm 10.38	0.117/0.503
	No	1.24 \pm 0.43		11.09 \pm 0.86		27.18 \pm 10.78	

Independent samples t-test analysis,* Mann-Whitney U test.

For the whole sample, the mean points of the self-reported ITAS, used to evaluate patient adherence to treatment, were found to be high at 11.03 ± 0.90 (range,

8.00-12.00), and the mean PSS-Fa points were high at 27.56 ± 4.94 (range, 0-38) (Table 3).

Table 3. Distribution of scale points.

	Minimum	Maximum	M±SD
ITAS	8	12	11.03±0.90
PSS-Fa	0	38	27.56±4.94

No statistically significant relationship was found between the drug adherence points obtained using the self-reported method (ITAS), the PSS-Fa, and the tacrolimus blood plasma level mean standard deviation value obtained with the biological evaluation method ($p > 0.05$). There was no correlation between age and the tacrolimus blood plasma level mean standard deviation value ($p > 0.05$). A significant negative relationship was determined between age and PSS-Fa ($p < 0.05$), and a significant positive relationship between age and the mean ITAS points (Table 4).

Table 4. Correlation analysis results.

		Correlation Matrix		
Variables		1	2	3
1.	Tacrolimus blood plasma level standard deviation mean	1	.081	-.058
2.	ITAS	.081	1	.079
3.	PSS-Fa	-.058	.079	1
4.	Age	-.053	.259**	-.246*

Pearson correlation analysis, * $p < 0.05$, ** $p < 0.001$.

DISCUSSION

The evaluation of drug adherence of transplantation patients by nurses using standardised measurement tools, the determination of reasons for non-adherence, and the implementation of interventions to improve drug adherence can increase the treatment success rates (26). Therefore, the aim of this study was to evaluate the effect of family support of patients on drug adherence. However, as no previous study could be found in literature which has investigated family support for immunosuppressive treatment adherence in an adult patient group, the current study findings were discussed in the light of the results of similar studies.

In a systematic review, Denhaerynck et al. (27) stated that young age was a reason for drug non-adherence. In another study, conflicting results were determined about whether or not age, gender, and time since transplantation were related to non-adherence (6). Through a period of 12 years after transplantation, it has been shown that patients with poor drug adherence have a higher risk of graft loss and mortality (28). Chisholm et al. (19) reported no correlation between immunosuppressive drug adherence and donor type, graft rejection rate, and time since transplantation. In the current study, there was found to be no effect on drug adherence of gender, education level, time since transplantation, donor type, and rejection attack status, but in patients aged ≤ 40 years, the mean ITAS points were determined to be low. The results of the current study were supported by findings in literature.

The effect of family relationships, the feeling of family support, and the support of family and friends have been reported to have a positive effect on disease

(24). Individuals with little social support can encounter many difficulties when coping with stress. The complex management of the drug treatment of kidney transplantation patients and their roles in daily life can increase the stress levels of patients. Therefore, it has been reported that social support can be effective in interventions made in respect of forgetfulness (29). By increasing depression in patients, a negative perception of social support has been reported to cause drug non-adherence (30). In a meta-analysis, which examined the results of 46 studies, poor social support was reported as a risk factor for non-adherence to drug treatment (31). Prihodova et al. (28) reported that perceived social support was high in the first year after transplantation and this was determined to be associated with full adherence to immunosuppressive treatment. It has been reported that males perceive a higher level of social support than females and the mean rate of social support perceived from the family and the seeking of social support increase with age (13). In the current study, the perception of family support of patients younger than 40 years was high and a positive relationship was determined between age and ITAS points. Family support was not determined to be affected by gender, the time since transplantation, donor type, and rejection attacks. In Islam, support of patients is encouraged, and it was thought that this together with the family structure and cultural traditions in Turkey encouraged the help given by close and distant family members, and friends, to eliminate the feelings of the patient of being alone and provided the necessary social support.

In a study by Tielen et al. (32) which investigated the effect of attitudes to drug treatment after kidney transplantation on drug adherence and graft survival, there was a relationship between graft rejection and drug non-adherence according to the self-reported statements of patients, but no relationship was determined with tacrolimus blood plasma level. Ordin et al. (18) determined high levels of drug adherence in the self-reported of patients. In a study by Patzer et al. (6) the rates of immunosuppressive treatment non-adherence were shown to be higher with patient self-evaluation than with other methods. According to the self-report scale of the current study (ITAS), the drug adherence of the patients was high.

Biological evaluation of drug non-adherence has the advantages of providing an objective, quantitative value. However, in evaluations such as this, only the drug level of the patient at that moment can be examined. The results obtained can be affected by the laboratory conditions, and diet or other drugs taken by the patient. It must also be taken into consideration that the patient could have taken the drug just before the clinical examination (18). It was reported by Patzer et al. (6) that 35% of patients did not show treatment adherence according to the biological (tacrolimus) measurements. In another study, the drug plasma level standard deviation value was < 2.47 in 80% of the patients and these were evaluated as drug-adherent (18). Accord-

ding to the biological evaluation in the current study, the mean tacrolimus plasma level standard deviation value of 72.4% of the patients was <2.47 , and thus the drug adherence of the patients was determined to be high. However, no correlation was determined between the mean tacrolimus plasma level standard deviation value and ITAS, the reasons for which could be that more care is needed about patients having taken the drug just before the clinical examination, or that patient drug adherence is reported as high in the self-reported method.

In a study by Baykal and Orak (2018) which investigated family support in glycemic control of type 2 diabetic patients, family support was found to be high for married patients and support from friends for single patients (33). Kelleci and Ata (2012) also determined that drug adherence points were higher in patients who felt they had support from friends or a significant person in their life (9). In a systematic review and meta-analysis by Ladin et al. (34) a weak correlation was determined between social support and treatment adherence after transplantation. Scheel et al. (35) reported that patients with little social support did not show treatment adherence. It has also been reported that social support can be used to eliminate drug non-adherence associated with forgetfulness (36). From the results of the current study, no correlation was determined between the mean tacrolimus plasma level standard deviation value, used as biological evaluation, and the mean ITAS and PSS-Fa points, used as the self-report method. This result could have been due to the patients receiving sufficient support from family or friends.

Strong aspects of the study can be considered to be that biological drug adherence of the patients was evaluated with a self-reported scale, and a scale was used in the evaluation of family support. The limitations can be said to be that the results cannot be generalized to the whole of Turkey as the research was conducted in a single centre.

Limitations with the Study

In this study, biological evaluation and the self-report scale method were used to evaluate patient drug comp-

liance. The scale was also used to evaluate family support. This research's strength lies in this. The results of this study cannot be generalized to all of Turkey because it was conducted in a single center. The limitations of this study are constituted by this situation.

Conclusion

In this study, biological and self-report methods were used with the aim of evaluating the drug adherence levels of patients, but no correlation was determined between the two methods. There was determined to be a relationship between age and ITAS points, and there was no relationship between family support and drug adherence. However, the drug adherence levels of the patients and their perceptions of family support were determined to be high. To further evaluate the effect of family support on drug adherence, prospective studies could be conducted with sample groups including different transplantation types.

Author Contributions

All the authors made equal contributions to the study.

Ethics Committee Approval

The study was conducted in accordance with ethical rules for research and publication.

All the study were procedures were applied in accordance with the 1964 Helsinki Declaration, national research committee ethical standards and subsequent revisions.

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Data Use

The data supporting the results of this study can be obtained from the corresponding author on request. For reasons of confidentiality and ethics, the data are not available to the public.

Conflict of Interests

The authors have no conflict of interests to declare.

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