

Knowledge, attitude and practices regarding pharmacovigilance among Turkish inpatients: A cross-sectional study

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Abstract: Background: Reporting adverse drug reactions (ADRs) by patients may contribute to the improvement of drug safety. However, underreporting of ADRs is estimated to be the main problem of the pharmacovigilance system. While the concern about and contribution to pharmacovigilance of Turkish health professionals is disappointing, drawing the picture of Turkish consumers' knowledge, attitude and practices is paramount to improve the contribution of this group. **Objectives:** We evaluated the knowledge, attitude and practices regarding pharmacovigilance among Turkish inpatients in a university hospital in Turkey. **Methods:** An observational, cross-sectional study was performed by a face-to-face questionnaire in 260 inpatients. The questionnaire consisted of demographic data and 15 and 9 items regarding knowledge and attitude and practices, respectively. The numerical and categorical data were presented as mean \pm standard error of the mean (S.E.M.) and number (percentage). Comparisons between two groups were analysed by Mann-Whitney U test and those between more than two groups by Kruskal-Wallis test and Dunn-Sidak test. **Results:** The mean score of knowledge level (1.38 ± 0.12) was far below that of maximum score (15 points). Although 245 of 260 inpatients (94.62%) were aware of side effects, only 18 of them (6.92%) had heard about the pharmacovigilance term and the Turkish Pharmacovigilance Centre. Ten of 18 subjects (55.56%) knew that they could directly report ADRs via the reporting form. 42% of inpatients had experienced ADRs in the past, 69.16% of them preferred to consult the doctor of concern, stopping the drug being the most selected intervention (60.75%). Among the 18 subjects aware of the Turkish Pharmacovigilance Centre, only 11.11% reported ADRs to the center. **Conclusion:** The knowledge, attitude and practices of Turkish inpatients regarding pharmacovigilance are insufficient and should be stimulated through various means to increase the rate of spontaneous reporting of ADRs and to ensure a more proactive attitude.

Keywords: Attitude; Advers drug reactions; Inpatients; Knowledge; Pharmacovigilance.

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INTRODUCTION

The World Health Organization (WHO) has defined pharmacovigilance as “the science and activities relating to the detection, assessment, understanding and prevention of adverse effects” (World Health Organization, 2002). In most countries, including Turkey, patients, in addition to healthcare professionals, are authorized to report adverse drug reactions (ADRs). However, underreporting of ADRs is estimated to be the main problem of the pharmacovigilance system (Campbell *et al.*, 2014; García-Abeijón *et al.*, 2023). For instance, a study conducted in Nepal showed that consumers' knowledge scores were quite low and an improvement should be achieved for the sake of drug safety (Jha *et al.*, 2017). Similarly, the authors concluded that the Chinese public had poor awareness about pharmacovigilance and showed imperceptions on the seriousness of ADRs, which were suggested to be the main reasons of underreporting (Chen *et al.*, 2021). Despite the lack of data regarding Turkish patients, previous studies conducted on Turkish pharmacists, nurses, midwives and physicians showed that knowledge,

attitude and practices (KAP) towards pharmacovigilance were very limited (Toklu and Uysal, 2008; Alan *et al.*, 2013; Vural *et al.*, 2014; Ergün *et al.*, 2019; Aydın *et al.*, 2023). While the concern about and contribution to pharmacovigilance of Turkish health professionals is disappointing, drawing the picture of Turkish consumers' KAP is paramount to improve the contribution of this group. Therefore, the present study was carried out to explore the knowledge about the Turkish regulations and executions and the attitude and practices regarding pharmacovigilance in those hospitalized in a university hospital.

MATERIALS AND METHODS

Study design and settings

A cross-sectional study was carried out in patients hospitalized in a university hospital in Turkey between January 2022 and November 2022 in line with Declaration of Helsinki (World Medical Association, 2013). Each participant gave written consent before the study. The inclusion criteria for participants were: hospitalization in an internal medicine ward, receiving medical treatment, being aged 18-65 years, willingness to participate in the study and cooperativeness. The

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exclusion criteria were as follows: being a health professional (physician, dentist, pharmacist, nurse and midwife) and not being able to provide adequate answers to the survey questions. A minimum sample size of 260 volunteers was targeted, with the prediction that one-way analysis of variance would be performed for at most 5 groups using G*Power software with $\alpha=0.05$, $\beta=0.80$, effect size=0.25. We utilized the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) cross sectional reporting guidelines (von Elm et al., 2007).

Questionnaire

It was prepared according to the regulations and guidelines published on the website of the Ministry of Health of Turkey and various related articles (Jha et al., 2017; Chen et al., 2021; Ergun et al., 2019; Ergün et al., 2022). In brief, it consisted of questions regarding demographic details, including gender, places of residence, age and education. The next part assessed the knowledge levels of the participants by using 15 questions: fourteen out of 15 questions were designed as “yes or no/no idea” and the last question was an open-ended one. Question four was only asked to participants who answered 'yes' to question three. Similarly, the fifth question was dependent on a positive response to the third question. Subjects were allowed to answer the remaining questions after an affirmative response to the fifth question. Every correct response was accepted to be one point and the scores were within a range of zero points and 15 points. In the last part of the questionnaire, attitudes and practices of the subjects were evaluated by means of several questions (from 16 to 24). If the 16th question was positive, the 17th question was asked to the participants. In relation to the 17th question, the attitude of the medical staff who were consulted for an ADR by the subject was evaluated by questions 18 and 19. After an affirmative response to question 19, the 20th question was directed to the subjects to determine the intervention preferred by the medical staff. The remaining questions (21-24) were for those who gave a positive response to question 3. The questionnaire was filled out by the investigators in a face-to-face manner.

Statistical analysis

The presentations of numerical and categorical data were as mean \pm standard error of the mean (S.E.M.) and number (percentage), respectively. After testing for normal distribution and homogeneity of variances by Shapiro-Wilk and Levene tests, comparisons between two groups (according to gender) were analysed by Mann-Whitney U test and those between more than two groups (according to place of residence, age and education level) by Kruskal-Wallis test and Dunn-Sidak test. All statistical analyses were done using SPSS 25.0 statistical package and p-values less than 0.05 were accepted as significant.

RESULTS

The demographic characteristics of the patients (n=260) are summarized in Table 1.

The study population's level of knowledge (numerical data) was very low, as the mean score (1.38 ± 0.12 points) was far below the maximum possible score of 15 points (Table 2). There were no significant differences between the total points obtained from groups structured according to gender (Table 2) (Mann-Whitney U Test, $Z = -1.377$; $p = 0.168$).

In contrast, three groups arranged according to age showed a statistically significant difference (Kruskal-Wallis Test, $\chi^2 = 13.974$; $p = 0.001$) and post-hoc tests showed significant differences between some groups (Table 2). Similarly, regarding the places where the subjects live, a significant difference occurred between the three groups (Kruskal-Wallis Test, $\chi^2 = 9.624$; $p = 0.008$) and post-hoc tests revealed significant differences between the city and village and between the town and village (Table 2).

Additionally, education level emerged as a prominent factor influencing the knowledge level since statistical analysis revealed a significant value across the groups (Kruskal-Wallis Test, $\chi^2 = 40.915$; $p < 0.0001$). Thus, university graduates obtained significantly higher scores than those with lower education levels (Table 2).

The details of the responses of the patients to the knowledge section of the questionnaire are outlined in table 3 as categorical data. Among the positive respondents to question 3 (n=18), 10 of them (55.55%) knew that they could directly report drug side effects to the Turkish pharmacovigilance centre and all of these 10 patients (100.00%) were aware of the drug side effect reporting form. Among those who gave affirmative answer to question 5 (n=10), the percentages of the correct responses to the remaining questions (6 to 15) were within the range of 0% and 100%.

As for practices (categorical data), 107 of the patients (41.15%) stated that they had experienced drug side effects previously (Table 4). Of these, 12 (11.21%) did not require consultation, while the others consulted doctors (74, 69.16%), dentists (4, 3.74%), pharmacists (9, 8.41%), nurses (7, 6.54%) and midwives (2, 1.87%) (Table 4). In this regard, 88 out of 95 subjects (92.63%) thought that the medical staff sufficiently took care of them (Table 4). In 87 cases (91.58%), the consultant changed the therapy regimen using one or more of the following options: the drug dose was reduced in 11 cases; the frequency of drug intake was decreased in 7 cases; the drug was discontinued in 65 cases; another drug was administered in 35 cases; the side effect was treated with another drug in 25 cases (Table 4).

Table 1: Demographic characteristics of the patients (n=260)

Characteristic	Number (n)	Frequency (%)
Gender		
Male	113	43.46
Female	147	56.54
Place of residence		
City (Province)	151	58.07
Town (District)	78	30.00
Village	31	11.92
Age		
18-34	98	37.69
35-50	74	28.46
51-65	88	33.85
Education		
None	25	9.62
Primary school	90	34.62
Secondary school	44	16.92
High school	50	19.23
University	51	19.62

Table 2: Knowledge score points of subjects

Characteristic	Mean \pm S.E.M. (Median)	P values
Overall	1.38 \pm 0.12 (1)	-
Gender		p=0.168
Female	1.51 \pm 0.18 (1)	-
Male	1.32 \pm 1.70 (1)	-
Age		p=0.001
18-34	1.85 \pm 0.26 (1)	-
35-50	1.16 \pm 0.16 (1)	p=0.024 (vs. 18-34)
51-65	1.28 \pm 0.21 (1)	p=0.001 (vs. 18-34)
Places of resident		p=0.008
City (Province)	1.50 \pm 0.18 (1)	-
Town (District)	1.48 \pm 0.24 (1)	p=0.011 (vs. village)
Village	0.84 \pm 0.07 (1)	p=0.010 (vs. city)
Education		
None	0.84 \pm 0.07 (1)	
Primary school	1.06 \pm 0.10 (1)	p=0.0001 (vs. university)
Secondary school	0.98 \pm 0.02 (1)	p=0.0001 (vs. university)
High school	1.26 \pm 0.22 (1)	p=0.004 (vs. university)
University	3.27 \pm 0.58 (1)	p=0.0001 (vs. none)

Mann-Whitney U Test and Kruskal-Wallis Test with Dunn-Sidak test were performed for two and more than two group comparisons, respectively.

Table 3: Responses of subjects to questions in knowledge section

No	Questions	Number of Yes	Percentage of Yes
1	Have you heard the term drug side effect?	246 of 260	94.62
2	Have you heard the term pharmacovigilance?	18 of 260	6.92
3	Are you aware of the Turkish Pharmacovigilance Centre?	18 of 260	6.92
	<i>If response to 3 is yes proceeded to 4!</i>		
4	Can the patient directly report drug side effects to the Turkish Pharmacovigilance Centre?	10 of 18	55.55
	<i>If response to 4 is yes proceeded to 5!</i>		
5	Are you aware of the drug side effect reporting form?	10 of 10	100
	<i>If response to 5 is yes proceeded to the remaining questions!</i>		
6	Can the reporting form be obtained from the internet?	8 of 10	80
7	Can filled reporting forms be sent to the centre by post?	4 of 10	40
8	Can filled reporting forms be sent to the centre by e-mail?	6 of 10	60
9	Can filled reporting forms be sent to the centre by fax?	3 of 10	30
10	Can drug side effects be reported to the centre online?	8 of 10	80
11	Can drug side effects be reported to the centre by phone?	8 of 10	80
12	Can cosmetic side effects be reported to the centre online?	7 of 10	70
13	Can vaccine side effects be reported to the centre?	9 of 10	90
14	Can herbal drug side effects be reported to the centre?	5 of 10	50
15	Within how many days must drug side effects be reported? (15 days is correct!)	0 of 10	0

Table 4: Responses of subjects in attitude and practice section

No	Questions	Number of Yes	Percentage of Yes
16	Have you ever experienced any drug side effect?	107 of 260	41.15
17	If YES, who did you seek advice from when you had a drug side effect?		
	Did not get advice	12 of 107	11.21
	Doctor	74 of 107	69.16
	Dentist	4 of 107	3.74
	Pharmacist	9 of 107	8.41
	Nurse	7 of 107	6.54
	Midwife	2 of 107	1.87
18	Did the person you reported your drug side effect take adequate care of you?	88 of 95	92.63
19	Did the person you reported your drug side effect change your treatment plan?	87 of 95	91.58
20	If YES, what were the changes made to your treatment plan?		
	Drug dosage reduced	11 of 87	12.64
	Daily intake frequency of drug reduced	7 of 87	8.04
	Drug cut off	65 of 87	74.71
	Another drug given	35 of 87	40.23
	Side effect treated with another drug	25 of 87	28.74
	Do not remember	7 of 87	8.04
21*	Have you ever reported a drug side effect to the Turkish Pharmacovigilance Centre before?	2 of 18	11.11
22*	If YES, what were the reasons?		
	Desire for getting additional information about the drug and its side effects	1 of 2	50
	Facing a serious side effect	1 of 2	50
	Difficulty in discussing side effects with the family physician or pharmacist	0 of 2	0
	Anger because of the side effects	1 of 2	50
	Desire for an intervention	0 of 2	0
	Desire for sharing the experience	2 of 2	100
	No mentioning of side effects in the instructions for use	0 of 2	0
	Concern about the health status	2 of 2	100
23*	If NO, what were the reasons?		
	Drug side effect was not serious enough	1 of 16	6.25
	Drug side effect was a known/expected one	5 of 16	31.25
	Apathy to drug side effect reporting	1 of 16	6.25
	Lack of confidence for causality assessment between the drug and the side effects	5 of 16	31.25
	It is not necessary to report drug side effects	0 of 16	0
24	What are your opinions about drug side effect reporting?		
	Reporting drug side effects may help prevent harm to others	18 of 260	6.92
	I feel responsible for reporting drug side effects	16 of 260	6.15
	If the drug side effect is serious, I will report it	17 of 260	6.54
	If the side effect of the drug is not stated in the instructions for use, I will report it	16 of 260	6.15
	Drug side effect reporting benefits me	18 of 260	6.92
	Drug side effect reporting contributes to drug development, research and scientific knowledge	17 of 260	6.54
	If I experience any drug side effects in the future, I will report the side effects	17 of 260	6.54

*The questions were asked to those who were aware of the Turkish pharmacovigilance centre.

Among those who were aware of the national pharmacovigilance centre (n=18), only 2 of them (11.11%) declared that they had reported a drug side effect to the corresponding centre as a matter of their attitude (Table 4). The main motives for reporting were sharing their experience and concern about their health condition (Table 4).

On the other hand, experiencing an expected side effect and a lack of confidence in assessing causality were two discouraging factors that prevented patients from reporting (Table 4). Finally, the responses regarding the opinion of the patients about side effect reporting were distributed relatively equally, with each option receiving around 6% of the responses (Table 4).

DISCUSSION

The present study clearly showed that although most inpatients were aware of drug side effects, they had a very low level of knowledge regarding pharmacovigilance and its related components. Furthermore, for those who had experienced a side effect, physicians were the primary consultants among other healthcare providers. Lastly, only a small number of them reported their drug side effects to the Turkish Pharmacovigilance Centre.

The knowledge section of the questionnaire in the present study consisted of items closely related to the patient-oriented aspects of the Turkish pharmacovigilance system. In this regard, the overall knowledge of inpatients was quite low, demonstrating the significant lack of awareness among them regarding pharmacovigilance. Additionally, city and town residents and university graduates obtained significantly higher scores than those from villages and those with lower education levels. Although not evaluated in the present study, this difference may be due to the higher health literacy levels of these participants in comparison to others. Presumably, higher health literacy will enable patients to better understand complex health information, including drug side effects and pharmacovigilance. Thus, most studies indicate that urban populations have higher health literacy levels than rural populations (Aljassim and Ostini, 2020). Consistent with this, a recent study in a Turkish province involving outpatients demonstrated a positive relationship between education level and health literacy (Timur and Metin, 2023). In support of this, patients with higher education were found more likely to be aware of national pharmacovigilance system of Portugal in a previous study (Matos *et al.*, 2015).

Specifically, only 18 out of 260 inpatients (7%) were aware of the Turkish Pharmacovigilance Centre, a ratio quite lower than that (44.1%) found in Portuguese patients (Matos *et al.*, 2015). Of these 18 inpatients, only 10 knew they could directly report drug side effects to the

center using the reporting form. This scenario highlights a significant gap between real-world practices and the objective of the Turkish regulatory authority, which is responsible for the widespread implementation of pharmacovigilance activities among patients. To encourage patients to become involved in the pharmacovigilance system, the regulatory authority should plan educational activities through television programs, social media and other platforms. In addition, the regulatory authority should motivate and support healthcare providers to educate patients in various clinical settings. Supporting this point, a previous study in the United Kingdom found that nearly half of patients learned about the reporting from a pharmacy, while 16.2% heard about it from their general practitioners (McLernon *et al.*, 2011). Among those learning from other sources, the most common reasons were having a healthcare background/professional knowledge or exposure through media like TV, radio and books.

Among the very small number of inpatients (n=10) who were aware of the drug side effect reporting form, most knew that the internet was the primary source for obtaining it. This was relatively consistent with the preference of Chinese patients regarding the ways in reporting ADRs: namely, telephone (58.4%), internet (30.7%), email (8.1%) and post (2.8%) (Chen *et al.*, 2021). Responses to questions about how to send the forms and whether side effects from cosmetics, vaccines and herbal products could be reported were quite satisfactory. However, these seemingly satisfactory responses can be misleading if one overlooks the fact that only a very small number of inpatients (n=18) were asked these questions because a correct answer to the preceding question regarding the awareness of the Turkish Pharmacovigilance Centre was a prerequisite. Thus, when considering the total number of the study group (n=260), the percentages of correct responses regarding reporting methods are extremely low. Additionally, none of these respondents were aware of the obligatory 15-day reporting deadline. A previous study, indeed, established a correlation between the length of time taken to report a side effect after its detection and the reporting method chosen, finding that phone reports involved a shorter time lapse than online or postal reports (McLernon *et al.*, 2011). It is probable that patient-preferred reporting methods will change and the reporting time lapse will decrease as digital methods evolve and patients become more familiar with these technologies.

Despite the lack of knowledge about pharmacovigilance, nearly half of the inpatients experienced side effects during their lifespan. According to a systematic review, the pooled prevalence of ADRs was 8.32% in patients of the primary care setting (Insani *et al.*, 2021). In addition, the prevalence of ADRs in Indonesia varied significantly, ranging from 0.9% to 99%, depending on the specific

drug, the duration of therapy and the dosage (Maharani and Yugatama, 2023).

These individuals preferred to consult their doctors at first, followed by pharmacists and nurses. A study in the UK found that the vast majority of patients first discuss a suspected side effect with their general practitioner (McLernon *et al.*, 2011). This behaviour is rooted in the belief that the physician who prescribed the drug is best equipped to assess the causality and manage the clinical situation. The fact that pharmacists and nurses were also consulted aligns with literature that recognizes their expanding roles. Pharmacists are often highly accessible and are a key source of information for patients about medications, while nurses are often the primary point of contact for hospitalized patients. Our data reinforces the multi-professional network patients rely on for health information.

Almost all inpatients were satisfied after these consultations and the medical staff generally took action in the management of the side effect(s). Discontinuing the drug was by far the most preferred intervention implemented by the doctors; other approaches, in order of preference, were exchanging the drug, treating side effects and reducing the dosage of the drug. Several studies have explored the relationship between patient satisfaction and a healthcare professional's response to an ADR report. When a provider takes a patient's concern seriously and takes action, satisfaction levels are typically high. A study conducted in Turkey, while focusing on pharmacists, found that patient education and active management of side effects were key factors in building trust and satisfaction (Toklu *et al.*, 2008). Another study found a strong correlation between patient satisfaction and the response of healthcare professionals: it highlights that patients who felt their ADR reports were taken seriously by their physicians were more likely to report satisfaction with their care (Matos *et al.*, 2015). A previous study showed that patients were satisfied with the feedback they received, whether personalized or general, indicating that any form of acknowledgement and information exchange contributes to a positive experience (Rolfes *et al.*, 2015). It was found in a recent study that the primary management method for physicians was drug withdrawal (84.7% of cases), which aligns perfectly with our finding that discontinuing the drug was by far the most preferred intervention (Srisuriyachanchai *et al.*, 2023).

Among those who were aware of the national pharmacovigilance centre (n=18), solely 2 of them declared that they had reported a drug side effect to the corresponding centre as a matter of their attitude. Although it is impossible to draw a definitive conclusion about the broader population from data derived from only two individuals, the main motives for reporting were

sharing their experience and concern about their health condition. In this regard, two studies of patients in the Netherlands and Portugal who had previously reported ADRs found that the primary reasons for reporting were sharing experiences, the severity of the reaction, concerns about their own health and the absence of the ADR in the patient information leaflet (Matos *et al.*, 2015; van Hunsel *et al.*, 2010). Similarly, the main reasons for utilizing the reporting form were that patients wished to transfer their experiences for the benefit of both other patients and pharmacovigilance, providing a distinct perspective from healthcare professionals. Dismissive attitudes and under-reporting by health professionals were also prominent motives for their actions (Anderson *et al.*, 2011).

On the other hand, experiencing an expected side effect and a lack of confidence in assessing causality were two discouraging factors that prevented 16 patients from reporting. In fact, the inherent difficulty for patients in differentiating between potential ADRs and symptoms of their underlying condition, which the suspected medication aims to treat, poses a significant challenge concerning the issue of causality assessment (McLernon *et al.*, 2010). This challenge could be mitigated by enhancing the general health literacy of patients and by healthcare professionals providing more comprehensive information regarding the disease and the associated medication.

Finally, most of the participants could not generate any opinion about side effect reporting, as response frequencies for each option were no more than 7%, which is in line with the data mentioned above regarding the lack of knowledge of pharmacovigilance. Nevertheless, the options presented in this questionnaire resonated with findings from a prior study, where most patients believed that reporting an ADR could prevent harm to others, contribute to research and knowledge and reflect their sense of responsibility and indicated that they will report a potential ADR in the future (van Hunsel *et al.*, 2010).

One of the limitations of the study was the exclusion of outpatients, which restricts the generalizability of the results to the entire patient population. As the health condition of inpatients is generally more serious than that of outpatients, inpatients may be more vigilant regarding the deleterious effects of drugs and more aware of the pharmacovigilance system. As a matter of fact, the overall level of vigilance and awareness regarding pharmacovigilance among all patients (including outpatients) may be lower than that observed in inpatients alone. Another limitation is that the questionnaire used to assess pharmacovigilance knowledge lacked formal validation as a scale. Consequently, the scores derived from this tool cannot be considered a precise or scientifically robust measure. However, they may still offer a relative reflection of the participants' knowledge levels.

In conclusion, the present data demonstrate that Turkish patients are not yet ready to participate in the pharmacovigilance system established by the national authority. For this to happen, the authority and related healthcare professionals should properly educate patients through various mechanisms to foster a positive attitude toward and practice of pharmacovigilance. Given the persistent issue of significant under-reporting of ADRs by healthcare professionals, the inclusion of patients in reporting processes may enhance spontaneous reporting and facilitate earlier detection of novel ADRs. Further, larger studies should be conducted to analyse the true levels of knowledge, attitude and practice among Turkish patients to enable rational actions aimed at overcoming these shortcomings.

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Authors' contributions

Tansel Bekiroğlu Ergün: Significant contributions to the work's conception, design, data acquisition, analysis, or interpretation; Drafting or critically revising for intellectual content; Final approval of the version to be published

Mine Akben: Significant contributions to the work's conception, design, data acquisition, analysis, or interpretation; Accountability for all work aspects, ensuring integrity and resolving questions

Yusuf Ergün: Significant contributions to the work's conception, design, data acquisition, analysis, or interpretation; Drafting or critically revising for intellectual content; Final approval of the version to be published; Accountability for all work aspects, ensuring integrity and resolving questions

Duygun Altıntaş Aykan: Significant contributions to the work's conception, design, data acquisition, analysis, or interpretation; Drafting or critically revising for intellectual content; Final approval of the version to be published; Accountability for all work aspects, ensuring integrity and resolving questions

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Data availability statement

The datasets generated during and/or analyzed during the current study are available in the Mendeley Data repository, [<https://data.mendeley.com/drafts/npjxkfsjhr>]

Ethical approval

The study was approved by the Clinical Trials Ethics Committee of the School of Medicine, Kahramanmaraş Sutcu Imam University (Verdict date: 02.20.2019; number/session: 13/03).

Conflict of interest

The authors state that there is no conflict of interest.

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