Caspian Journal of Neurological Sciences
http://cjns.gums.ac.ir

The Applicability, Concurrent Validity and Internal Consistency Reliability of the Persian Version of the National Institutes of Health Stroke Scale (NIHSS): Evidences for Gender Differences

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ARTICLE INFO

Article type:
Original Article

Article history:
Received: 29 September 2015
Accepted: 20 November 2015
Available online: 6 March 2016
CJNS 2016; 2 (4): 18-28

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ABSTRACT

Background: The National Institutes of Health Stroke Scale (NIHSS) can objectively quantify the severity of stroke. However no information is available about psychometric properties and it's applicability in the Iranian population.
Objectives: The present study purposed by utilization of this instrument for neurological deficits measurement due to stroke, to determine the internal consistency reliability and concurrent validity of NIHSS to separate two groups of men and women patients.
Materials and Methods: In a cross-sectional study, 206 ischemic stroke patients were selected and the internal consistency reliability and concurrent validity of NIHSS were assessed. For this purpose, Barthel index that measures the functional disability was used. Data also were analyzed by Independent t-test, Chi-square, Pearson correlation, Fisher's z tests and bivariate regression analysis.
Results: Internal consistency for men (α=0.881), women (α=0.913) and total patients (α=0.893) was excellent. Negative correlation was found between NIHSS and Barthel index in both men (r=-0.43, p<0.0001) and women (r=-0.63, p<0.0001) and this relationship estimated to be more significant among women rather than men (p<0.05). In addition, NIHSS scores could significantly predict the Barthel score in both groups (p<0.0001) but the results revealed the more ability of NIHSS in predicting functional disability for women (R^2=0.40) rather than men (R^2=0.18).
Conclusion: Persian version of NIHSS was reliable and valid instrument that can be applicable in both men and women with ischemic stroke; however, it was found that the degree of concurrent validity is better among women than men.

Keywords: Reliability; Validity; Stroke; Scale

➢ ***Please cite this paper as:***
Kazemnejad-Leili E, Rezaei S, Hosseini-Nejad M, Bakhshayesh-Eghbali B, Saberi A, Keshavarz P. The Applicability, Concurrent Validity and Internal Consistency Reliability of the Persian Version of the National Institutes of Health Stroke Scale (NIHSS): Evidences for Gender Differences. Caspian J Neurol Sci 2016; 2(4):18-28.

Introduction

Stroke scales are used in clinical researches for aggregating and grading the deficits found in stroke patients. Stroke scales are useful for documenting the trend of deficit formation in patients (at baseline and also notation of the changes occurring over time); and provide information for healthcare teams in order to determine the prognosis. These scales are even more beneficial in studies that aim to ensure the equal severity of stroke among different groups of patients and to also provide a measure of disability outcomes. Ideally, a stroke scale should be simple and quick to implement, have a high level of inter- and intra-rater repeatability, and provide the useful prognostic information (1). The National Institutes of Health Stroke Scale (NIHSS) is a well-known scale proposed by the United States National Health Institute that is used in cases of acute stroke as a relevant and sensitive tool for assessing the severity of the disorder and to make informed medical and nursing decisions (2).

The NIHSS presents an integrated picture of the neurological deficits measured in stroke patients. This scale also provides a quick, effective, accurate and systematic assessment of stroke patients and is used extensively in the evaluation of the patients' treatment and hospital care plans and in the development of rehabilitation programs and the review of the change of patients' condition (2). The NIHSS is one of the four neurological scales used in the assessment of fibrinolytic therapy outcomes (3) and is composed of 15 independently-scored items. In general, the NIHSS includes the items to measure the level of consciousness (LOC) (3 points), LOC questions (2 points), LOC commands (2 points), best gaze (2 points), visual(3 points), facial palsy (3 points), motor arm (4 points, to the right and left), motor leg (4 points, to the right and left), limb ataxia (2 points), sensory (2 points), best language (3 points), dysarthria (2 points) and extinction and inattention (2 points). The total score of the scale is the sum of scores obtained in all the 15 items, ranging from 0 to 42 (2). Completing the scale takes 5 to 8 minutes (4).

Studies have demonstrated that the baseline severity of patient neurological deficits as measured by the NIHSS is the strongest predictor of the final outcome (1). In other words, higher scores on the scale indicate worse or more severe neurological deficits (2). Schlegel *et al.* found that patients with higher NIHSS scores have a 21% lower chance of getting discharged from the hospital and a 31% greater chance of using care facilities in the long-term (5). Spilker *et al.* showed that, in patients over the age of 77, NIHSS scores in excess of 22 are linked to an increased risk of mortality and intracranial bleeding after treatment (4).

Psychometric studies of the NIHSS have confirmed its high internal consistency reliability and concurrent validity (2,6). Brott *et al.* examined the concurrent validity of the NIHSS through determining the relationship between the scores obtained in the this scale and the volume of cerebral infarction in the patients as assessed by the computer tomography (CT) scan and found it to be 0.74 after one week (6). In a similar study, Schiemanck *et al.* disclosed the correlation between the NIHSS scores and the volume of cerebral lesion in the patients as assessed by MRI and reported it to be 0.61 after two weeks (7), indicating the acceptable validity of the NIHSS. As for the inter-rater agreement of the scale, Goldstein *et al.* reported a poor reliability for four

of its items (including facial palsy, limb ataxia, extinction and inattention and the best gaze), but calculated its Kappa Coefficients to be above 0.42 for the remaining items (8). Studies have shown an excellent inter-rater agreement (mean K=0.69) and a good intra-rater agreement (mean K=0.77) for the NIHSS, especially when the rater is a trained neurologist (1). Williams *et al.* reported the inter-rater reliability of the NIHSS as 0.98 and the inter-rater agreement level for each of its subscales as good to excellent (9).

Applicability is a type of external validity that denotes how much the results of a test are applicable or generalizable to other groups or populations (10). Despite the extensive advantages and the wide use of the NIHSS, the assessment of this scale among Iranian patients appears to have been generally neglected. Furthermore, none of the studies conducted on this scale to date have reported the relationship between the reliability and validity of the scale and the patients' gender differences. The present study thus intends to use the NIHSS to assess post-stroke neurological deficits and to then determine the internal consistency reliability and concurrent validity of the scale by gender differentiation.

Materials and Methods

As part of a more extensive research on patients with ischemic stroke, the present cross-sectional study was approved by the Ethics Committee and the Research Council of Guilan University of Medical Sciences (No. 93031202 and dated 23.05.2014). Participants were selected by the phone contact from patients with a definitive diagnosis of ischemic stroke and discharged over the past two years from the neurology ward of a teaching hospital affiliated with Guilan University of Medical Sciences in northern Iran. Patients with records spanning April 2012 to May 2014 entered the study.

A total of 760 patients that their medical documents recorded in the Hospital Information System (HIS) during the two years preceding the study were identified. Telephone interviews conducted with the patients or their caregivers helped screen the deceased patients or those with severe language deficiency, severe physical disability or severe dementia or amnesia. Prior to the assessments, the English version of the NIHSS was accessed through the American National Institute of Neurological Disorders and Stroke website (https://www.ninds.nih.gov/doctors/NIH_Stroke_Scale.pdf) (3) and translated into Persian by the study's corresponding author. The Persian and English versions were then reconciled by a neurologist. The face and content validity of the Persian version of the NIHSS for the assessment of stroke patients was confirmed by three expert neurologist of Guilan University of Medical Sciences.

The severity of neurological deficits in stroke patients was evaluated using the NIHSS and their post-stroke functional disability was assessed as an outcome variable using the Barthel Index (11). The validity and reliability of the Persian version of the Barthel index has already been confirmed in other studies (12). The patients were contacted over the phone and asked to be visited at the neurology clinic affiliated with Guilan University once again to be examined by a neurologist.

The study inclusion criteria consisted of 1) having had an ischemic stroke confirmed by a neurologist using a CT scan or cerebral MRI based on the WHO diagnostic criteria (13), 2)

having the ability to complete the assessments and tests required by the study and 3) the patient or his/her legal guardian giving an informed consent for participation in the study. The study exclusion criteria consisted of 1) having severe diseases or a severe consciousness deficit, 2) having severe hearing or vision impairments leading to absence from or non-cooperation in the tests and assessments and 3) having had dementia or other neurological disorders prior to the stroke (such as seizures and Parkinson's disease).

Stroke risk factors, including obesity (BMI>30), previous history of stroke, a family history of stroke and a history of Transient Ischemic Attacks (TIA), were obtained from the patients' medical files and were approved by outpatient examinations. Other stroke risk factors such as having hypertension, diabetes mellitus, hyperlipidemia, Ischemic Heart Disease (IHD) and cardiac arrhythmia were recorded for the patients through the confirmed diagnosis in their past medical history or the results of two turns of blood pressure examinations, serum glucose level, and serum lipid profile after admission at the hospital. Moreover current prescription of anti-hypertensive, glucose lowering and lipid lowering drugs was also considered.

Patients with pre-stroke dementia were excluded from the study irrespective of the type and etiology of their condition. For this purpose, the patients' premorbid cognitive function was assessed by asking a relative of theirs or someone who knew the patient for at least 10 years to complete the Persian version of the 26-item Informant Questionnaire on Cognitive Decline in the Elderly (IQCODE) (14). Several studies have confirmed the validity and reliability of the IQCODE and its ability to distinguish between patients with dementia and those without the condition (15). Tang *et al.* have shown that, with a cutoff point of 3.4, the IQCODE is able to identify dementia with 88% sensitivity and 75% specificity during the three months succeeding a stroke (16). Barba *et al.* used the IQCODE to detect pre-stroke dementia and found that its scores can predict death and incident dementia in patients during the three months succeeding their stroke (17). To identify patients with pre-stroke dementia in present research, all the premorbid data available on the patients were used, including the data obtained through conducting interviews with their caregivers or first-degree family members, collecting their medical history from the hospital records, examining their medical regimens and, more importantly, performing the IQCODE and detecting scores greater than the cutoff point of 3.4.

Sample size was determined using the equation for estimating the mean trait in a population (18). In a pilot study conducted on 30 patients, the standard deviation of the severity of neurological deficits in stroke patients was calculated as 2.34; this value was then inserted in the following sample size calculation formula with the confidence interval of 0.99 (Z=2.58) and the acceptable error (d^2) of 0.45, the sample size required for the present study was thus estimated as 182.55, which was then extended to 200 to account for a dropout rate of 10%.

$$n = \frac{Z^2_{1-\frac{\alpha}{2}} S^2}{d^2} = \frac{(2.58)^2 \times (2.34)^2}{(0.45)^2} = 182.15 + 10\%\, dropout = 200$$

Physical and neurological assessment

The severity of the stroke and the neurological deficits was assessed using the

NIHSS, with scores ranging from 0 to 42 and with higher scores indicating a greater neurological impairment (6, 19). The data pertaining to the severity of the stroke was not available for all patients at the time of admission and measuring the neurological deficits caused by stroke was possible only after the patients' discharge and when they re-visited at the clinic. The Barthel Index was used to measure the patients' functional disability as an outcome of stroke and also to assess the concurrent validity of the NIHSS. This index was first designed in 1965 to measure individuals' performance in Activities of Daily Living (ADL) (20) and was later modified by Granger *et al.* (11). This tool measures functional disability by quantifying the patients' performance in 10 ADL. These activities can be classified in terms of the self-care (eating, bathing, appearance, dressing, bowel and bladder control and bathroom visits) and mobility (moving from the bed to the chair and vice versa, moving on levels and moving up and down the stairs) functions. Each of the 10 activities is scored from 0 to 5 or from 0 to 15 and the highest score obtained is 100. Higher scores indicate independence in physical functioning. The scale takes a maximum of 5 minutes to be completed, which can be done by a nurse, a friend or a close relative of the patient and without the need for the patient's own direct observation. This scale has high inter-rater and test-retest reliabilities (with coefficients of 0.95 and 0.89 respectively) and a strong correlation with other physical disability measurement tools, ranging from 0.74 to 0.8 (21).

Statistical Analysis

The independent student *t*-test and Pearson's Chi-squared test (χ^2) were used to describe and compare the male and female groups of patients in terms of age, NIHSS score, the Barthel Index and ischemic stroke risk factors. The internal consistency reliability of the NIHSS was calculated using Cronbach's alpha coefficient for the female and male group of patients separately and the entire group of patients. To assess the concurrent validity of the NIHSS, its correlation with the Barthel index was first calculated separately by gender and then, to find the significance of the difference between the correlation coefficients obtained in the two independent groups of male and female patients, Fisher's Z test was used with the following formula and at the significance level of 0.05: $Z = \frac{Zr1 - Zr2}{\sqrt{\frac{1}{n1-3} + \frac{1}{n2-3}}}$ (22). The results are shown in the form of a figure using the bivariate regression analysis (with the NIHSS and the Barthel index serving as the two variables) for the groups of male and female patients. All the statistical analysis was performed in SPSS software version 20.

Results

A total of 206 patients with ischemic stroke and with a mean age of 64.52±11.71 (ranging from 40 to 89) years consented to participating in the present study. One hundred seven (51.9%) of the participants were male and ninety-nine (48.1%) were female. There were no significant differences in terms of age and gender between participants and the patients screened at the beginning of the study ($p>0.05$). Table 1 compares the mean age, NIHSS score and Barthel index obtained in the two groups of patients with ischemic stroke by gender.

Table 1: The results of the independent *t*-test for the group of male (n=107) and female (n=99) patients with ischemic stroke in terms of age, NIHSS score and the Barthel index

Characteristics	Gender	SD	M	t	*p-value*
Age	Males	11.72	64.84	-0.40	0.688
	Females	11.76	64.18		
NIHSS	Males	2.18	2.15	2.12	0.035
	Females	2.80	2.89		
Barthel Index	Males	17.03	91.35	-3.67	0.0001
	Females	27.16	79.65		

The independent t-test showed a significant difference between the groups of male and female patients in terms of the NIHSS score and the Barthel index. This means that the female patients had experienced a more severe neurological damage rather than male patients (p=0.035) and a higher level of functional disability (p<0.0001) following their ischemic stroke. However, no significant differences were observed between the groups of male and female patients in terms of age (p=0.688). Table 2 compares the two groups in terms of the frequency of the stroke risk factors.

Table 2: The frequency of the stroke risk factors in the groups of male and female patients (n=206)

Characteristics		**Males**		**Females**		**χ2**	***p-value***
		n	**%**	**n**	**%**		
Obesity (BMI≥ 30)	Yes	7	6.5	34	34.3	24.93	0.0001
	No	100	93.5	35	65.7		
History of stroke	Yes	24	22.4	27	27.3	0.65	0.421
	No	83	77.6	72	72.7		
Family history of stroke	Yes	39	36.4	33	33.3	0.22	0.639
	No	68	63.6	66	66.7		
History of TIA	Yes	23	21.5	22	22.2	0.02	0.900
	No	84	78.5	77	77.8		
Hypertension	Yes	71	66.4	80	80.8	5.49	0.019
	No	36	33.6	19	19.2		
Diabetes mellitus	Yes	34	31.8	50	50.5	7.47	0.006
	No	73	68.2	49	49.5		
Hyperlipidemia	Yes	36	33.6	45	45.5	3.01	0.083
	No	71	66.4	54	54.5		
Ischemic heart disease	Yes	37	34.6	41	41.4	1.02	0.312
	No	70	65.4	58	58.6		
Atrial fibrillation	Yes	26	24.3	22	22.2	0.12	0.725
	No	81	75.7	77	77.8		

As shown in table 2, no significant differences were observed between the groups of male and female patients with ischemic stroke in terms of their stroke risk factors, such as a previous history of stroke, a family history of stroke, transient ischemic attacks (TIA), hyperlipidemia, ischemic heart diseases and atrial fibrillation (p>0.05). Nevertheless, Pearson's Chi-squared test showed a significant difference between the groups of male and female patients in terms of obesity as signified by a BMI equal/above 30 (χ^2=24.93, df=1, p<0.0001), hypertension (χ^2=5.49, df=1, p=0.019) and diabetes mellitus (χ^2=7.47, df=1 , p=0.006). This means that compared to men, a higher percentage of women suffered from obesity (34.3% *vs.* 6.5%), hypertension (80.8% *vs.* 66.4%), and diabetes mellitus (50.5% *vs.* 31.8%).

The Cronbach's alpha coefficients obtained for determining the internal consistency reliability of the NIHSS were 0.881, 0.919 and 0.893 for the groups of male and female patients and the entire group of patients respectively. With regard to sample size and based on Streiner and Norman's comments, these coefficients are acceptable (23). Salter

et al. believe Cronbach's alpha coefficient equal to or above 0.8 to be excellent, especially for tools assessing rehabilitation factors among stroke patients (24). The calculated Cronbach's alpha values for the groups of male and female patients and the entire group of patients with ischemic stroke thus indicated a good internal consistency reliability of NIHSS.

To assess the concurrent validity of the NIHSS in the groups of male and female patients with ischemic stroke, its correlation with the Barthel index was first assessed separately in which the results demonstrated a negative and significant correlation with the Barthel index in both groups of male patients (r= -0.43 and p<0.0001) and female patients (r= -0.63 and p<0.0001). The negative correlation was attributed to how, higher scores on the NIHSS meant greater neurological damage and higher scores on the Barthel index showed a lower functional disability. Fisher's Z test was then used to find the significance of the difference between the correlation coefficients obtained in the groups of male and female patients, in which values of r_1 and r_2 were converted into Z_{r1} and Z_{r2} using Fisher's table (22) and the data obtained were then inserted in the below equation and the final result was thus obtained as follows:

$$\textbf{Fisher}'\textbf{s Z} = \frac{0.460 - 0.741}{\sqrt{\frac{1}{107-3} + \frac{1}{99-3}}} = -1.99$$

Fisher's Z test showed significant differences between the correlation coefficients obtained in the groups of male and female patients with ischemic stroke at the significance level of p<0.05 and using the two-tailed test (Z=-1.99 and p=0.046). These findings clear that the correlation between the NIHSS scores and the Barthel index is stronger in the group of female patients compared to male patients group. The bivariate regression analysis was performed to determine what scores in the NIHSS (as the predictor variable) can explain variances in the Barthel Index scores (as the criterion variable) in the groups of male and female patients with ischemic stroke separately. Figure 1 represents the results obtained from the bivariate regression analysis and the difference in the slope of the line in two groups of male and female patients.

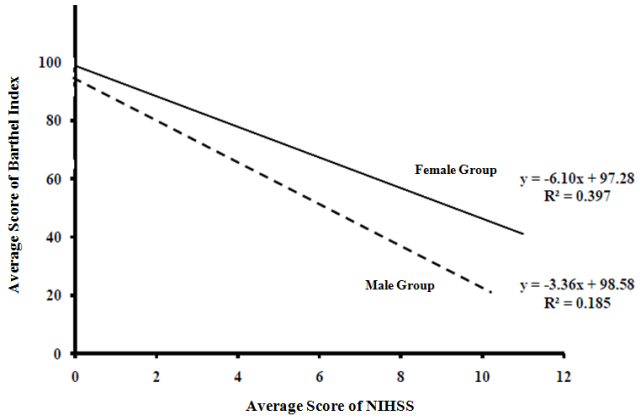

Figure 1: The slope of the line and the prediction equations for the Barthel scores from the NIHSS scores in two groups of male (n=107) and female (n=99) patients

The results of the bivariate regression analysis showed that NIHSS scores can significantly explain the variance of the Barthel Index scores in both groups of patients with ischemic stroke (p<0.0001). According to figure 1, the coefficients of determination obtained in the two groups show that the NIHSS is a stronger predictor of functional disability as measured by the Barthel Index in female (R^2=0.40) than in male (R^2=0.18) patients.

Discussion

The NIHSS is known as a valid scale for predicting the amount of brain lesion and can also be used to assess the severity of the stroke. Nevertheless, there is no evidence on the applicability and other psychometric features of this tool among Iranian patients, especially with respect to gender differences. The present study used the NIHSS to assess post-stroke neurological deficits and to also determine the internal consistency reliability and concurrent validity of this tool in male and female groups of patients.

The descriptive results obtained through comparing the two gender groups showed no significant differences between them in terms of age or stroke risk factors such as a previous history of stroke, a family history of stroke, Transient Ischemic Attacks (TIA), hyperlipidemia, ischemic heart diseases and atrial fibrillation; the two groups were therefore matching in the majority of the risk factors. In contrast the female patients examined, experienced more severe neurological deficits and a greater functional disability after the stroke compared to the male patients. The differences observed between the two groups in the concurrent validity coefficients obtained may be partly due to the greater vulnerability of women to certain stroke risk factors such as obesity, hypertension and diabetes mellitus (Table 2).

The Cronbach's alpha coefficients obtained for the groups of male and female patients and also the entire group of patients with ischemic stroke (0.881, 0.919, and 0.893, in respective order) suggests that the Persian version of the NIHSS performed by a neurologist has good internal consistency reliability for the all sample population. These results show that each of the NIHSS items have the required level of congruence and uniformity to assess the general concept of neurological deficits. In other words, each of the items measures the same structure and no redundancy is observed in them. Although the lack of similar studies on the reliability of the NIHSS by gender and also only a few studies have examined the internal consistency reliability of this scale, the review of these studies revealed the agreement with the present study. In one study, Sun *et al.* assessed the validity and reliability of the Chinese version of the NIHSS in 48 patients with ischemic stroke and found a Cronbach's alpha value of 0.92 for the scale, which agrees closely with the value found in the present study (2).

The concurrent validity of the NIHSS showed a negative and significant correlation with the Barthel Index in both the groups of male (r=-0.43) and female (r=-0.63) patients. Fisher's Z test showed a significant difference between the correlation coefficients obtained in the two groups (p<0.05), which was much stronger in the female group compared to in the male group. The results of the bivariate regression analysis showed that NIHSS scores can predict Barthel Index scores in groups of male and female patients with ischemic stroke; however, its ability to predict functional disability was found to be stronger in the female group compared to in the male group. The NIHSS thus has a greater concurrent validity in the group of women than in the group of men; nonetheless, it can generally be used as a valid and efficient tool to predict a moderate level of functional disability as a major consequence of stroke. In line with these results, Frankel *et al.* showed that patients with more severe neurological deficits (as assessed by the NIHSS) have a worse prognosis and more likely identified as

a subset of patients with high degrees of poor outcomes in the first week following their acute stroke (25). Sun *et al.* assessed the concurrent validity of the NIHSS and found a negative significant correlation between this scale and the Barthel Index (r=-0.683) (2). Meyer *et al.* assessed the concurrent validity of the NIHSS through determining its correlation with the Barthel Index, which was found to be weak but significant association (r=-0.165) (26). Also Leyden *et al.* estimated this correlation=-0.48 immediately after the stroke and=-0.58 two hours after the incident (27), which is closely in line with the correlation obtained in the present study. Brott *et al.* confirmed the concurrent validity of the NIHSS through determining its correlation with the volume of cerebral infarction in 65 stroke patients by computed tomography (r=0.74) (6). Lyden *et al.* and also Saver *et al.* conducted similar studies to assess the concurrent validity of the NIHSS and reported the correlation between the scores of this scale and the volume of cerebral infarction in stroke patients as r=0.37 and r=0.54, respectively (28, 29).

In line with the present research, previous studies conducted with different methods also emphasized the accuracy of the results obtained through the NIHSS and confirmed its concurrent validity. However, no studies were found that had performed this assessment from a gender-based perspective. The differences observed in both the stroke risk factors (table 2) and in the concurrent validity coefficients obtained in the groups of male and female patients may therefore be explained through the differences in the severity of neurological deficits (as indicated by the NIHSS scores) in the two groups (table 1); since it has already been proved how mild neurological deficits measured by the NIHSS can reduce the concurrent validity of the scale in relation to the Barthel Index (25).

The limitations of the present study included the unavailability of records of NIHSS scores obtained by the patients upon admission. Moreover, the present study was conducted solely on patients with ischemic stroke and its results cannot be generalized to patients with the other types of stroke; however, these findings can be used as a basis for future comparisons in Iranian patients. The inter-rater reliability of the scale should be assessed in future studies and a comparison be made between the NIHSS at the times of admission and discharge.

Conclusion

Overall, the results of the present research confirmed that the Persian version of the NIHSS is a valid and reliable tool that applies to both male and female patients with ischemic stroke; nevertheless, it should be noted that the concurrent validity of the scale is stronger in the group of female than male patients.

Acknowledgements

The present study was an approved research project by Guilan University of Medical Sciences (GUMS). Hereby, the authors would like to express their gratitude to the Research and technology vice-chancellorship of GUMS. Also we would like to thank the colleagues in the clinical researches and development center of Poursina Hospital for their support for sampling from the stroke patients.

Conflict of Interest

The authors have no conflict of interest.

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