Reliability and Validity of Turkish Version of Headache Impact Test (HIT-6) in Patients with Migraine

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ABSTRACT

Introduction: The Headache Impact Test (HIT-6) is a self-report questionnaire designed to evaluate the impact of headache on quality of life. The aim of this study is to assess reliability and validity of Turkish version of HIT-6 questionnaire in patients with migraine.

Methods: A total of 114 patients with migraine were included in this multicenter, prospective, descriptive study conducted at two consecutive visits 4 weeks apart. Comprehensibility, patient-physician reliability, internal consistency, test-retest reliability and validity of the translated HIT-6 were analyzed.

Results: Patients identified that HIT-6 items were "well-understood" in both visit 1 (ranged from 88.6% to 95.7%) and visit 2 (ranged from 93.0% to 98.2%).

A highly positive correlation (R=0.876, p<0.001) was noted between visit 1 scores related to self-administered and physician-administered HIT-6

scores. Internal consistency analyzed via Cronbach's α values for visit 1 and visit 2 HIT-6 scores in all patients were 0.753 (acceptable) and 0.864 (excellent), respectively. HIT-6 scores of patients (64.13 (6.20) and 62.70 (7.04), at visits 1 and 2, respectively, p=0.07) showed a moderate test-retest reliability (R=0.437, p=0.0004). The HIT-6 score positively correlated with visit 1 and visit 2 headache severity-Likert scale (R=0.451 and 0.478, respectively, p<0.001) and VAS (R=0.365 and 0.531, respectively p<0.001) scores, and with visit 2 headache days for a month (R=0.215, p=0.022).

Conclusion: These results demonstrated that the Turkish translation is equivalent to English version of HIT-6 in terms of internal consistency and it has moderate test-retest reliability and validity as correlated with headache severity, VAS and headache days for a month.

Keywords: Headache impact test, migraine, quality of life, HIT-6, MIDAS, headache

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INTRODUCTION

Migraine is a chronic, neurovascular disease characterized by heterogeneous clinical features with a strong genetic basis (1–3). Though not life-threatening but often detrimental to a patient's ability to carry out everyday activities, migraines are the third most common disease worldwide, and have been ranked as the sixth highest amongst all other causes of disability (4–7).

Owing to their significant role in accurate diagnosis and appropriate treatment of migraines, the use of Patient Reported Outcome (PRO) tools has been recommended by clinical and regulatory guidelines for better disease management in terms of diagnosis, screening, monitoring of quality of life, as well as identification of disease-related disability and selection of appropriate treatment (8–11).

For migraine patients, there are two PRO tools that have been widely used in clinical practice and trials (12–14): Headache Impact Test (HIT-6) and Migraine Disability Assessment questionnaire (MIDAS). For disability assessment, MIDAS was developed to cover the three activity

domains, which include schoolwork, jobs, and household chores, as well social, leisure, and family activities (12). The reliability and validity of MIDAS were demonstrated by Stewart et al. (12, 15, 16). Ertas et al. were performed reliability and validity of the Turkish MIDAS in 2004 (17).

The HIT-6 is a brief questionnaire designed by Bayliss et al. to assess migraine pain from the patient's point of view and to track lost time (work, school work, housework, social activities) (18). Both tools are scientifically valid measurements of migraine severity, and are also used to evaluate treatment effectiveness (19).

HIT-6 is considered to be a more subjective tool, as it reflects patients' own evaluation of headache severity on their quality of life. MIDAS, on the other hand, is more objective compared to HIT-6, as it questions the frequency of days affected by headaches rather than the disability expressed by the patients themselves (20). Moreover, in addition to covering a wider swath of the headache spectrum than MIDAS, HIT-6 has only six questions enabling easier completion of the patient's task and a shorter recall period (19–21).

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The translation process for HIT-6, performed by Gandek et al. in 2003 in terms of comparability of the content of the 27 translations involved, revealed HIT-6 to be relatively easier to translate, and was deemed to be clearer and more relevant by the respondents (22). However, while after the translation stage, psychometric properties and equivalence of the HIT-6 were examined for 11 languages in 14 countries (Brazilian Portuguese, UK English, Canadian English, Hungarian, Spanish, Dutch, Finnish, French, German, Greek and Hebrew) (14), the reliability and validity of the Turkish version of HIT-6 has not yet been studied. Hence, while the Turkish translation of HIT-6 has been available as an assessment tool for patients with migraines in daily clinical practice since 2003, it has rarely been used for research. For the current study, the English version of HIT-6 was translated to Turkish once again, instead of using the 2003 version of Turkish translation.

This study was therefore designed to assess the efficacy of the Turkish translation as it compared to its original (English) version, based on assessing the patient-physician reliability, test-retest reliability, internal consistency, comprehensibility and validity of the Turkish version of HIT-6 the questionnaire in patients dealing with chronic and episodic migraines.

METHODS

Study Population
Between November 2017 and April 2018, multicenter, prospective, and descriptive studies were conducted at three headache centers in Turkey, and included 114 adults diagnosed with migraines. Migraine diagnosis was made by three neurologists (PYD, DU, AO) with expertise in headaches using the International Classification of Headache Disorders criteria, third edition (ICHD3 beta). Patients with episodic or chronic migraines were included in the study, regardless of whether or not they had received preventive oral medication, while for those under preventive oral medication initiation of the treatment for at least three months prior to enrollment was required for the inclusion. The presence of acute and chronic psychosis, mental retardation and illiteracy, lack of follow-up visit or unwillingness to participate were the exclusion criteria. Of 138 patients initially enrolled, 24 patients were excluded due to loss of follow up (n=14) or unwillingness to participate in the study (n=10) and the final study population subjected to analysis involved 114 patients (Fig 1). Episodic migraines were defined as experiencing an average of up to 14 headache days each month for the past three months. Chronic migraines were defined as headaches occurring ≥15 days per month for a minimum of 3 months, of which ≥8 days met the criteria for a migraine.

Written consent was required from each participant, following a thorough debriefing of the study's objectives and procedures, carried out according to the ethical principles outlined in the "Declaration of Helsinki" and endorsed by the institutional ethics committee.

Study Design and Measures
The study was conducted at two consecutive visits including visit 1 (performed at baseline) and visit 2 (performed 4-weeks after the visit 1). Data on sociodemographic and headache characteristics and MIDAS scores were recorded at visit 1, and patients were asked to return the headache diaries for visit 2. All patients were assessed for visual analogue scale (VAS) for pain intensity, Likert scale for headache severity during daily activities and self-administered scores on comprehensibility assessment form (CAF) and HIT-6 at both visits. Physician-reported CAF scores and physician-administered HIT-6 were also recorded at visit 1 for a subgroup of patients (subgroup A, n=57) who were selected via 1:1 randomization of overall study population. Comprehensibility, validity, test-retest reliability and, patient-physician reliability, and internal consistency of the translated HIT-6 were analyzed (Figure 1).

Severity Frequency and Intensity of Headache
Assessment of the severity of patients' headaches was made using a 4-point Likert scale scored from (0) no, (1) mild, (2) moderate and (3) severe pain.
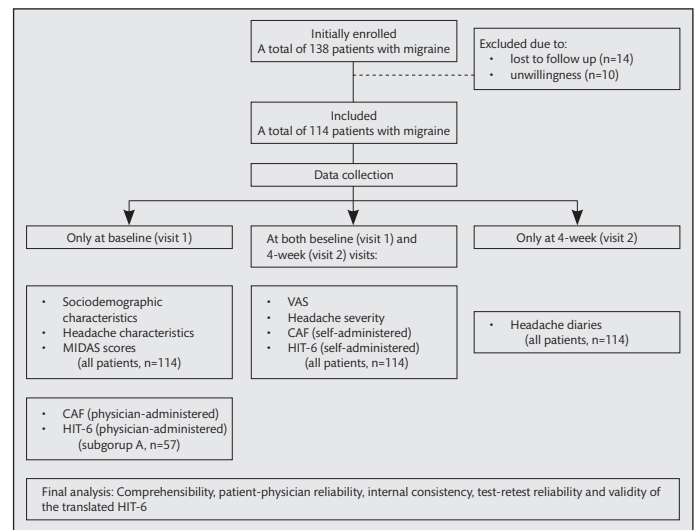

Figure 1. Study design and data collection.

The frequency of headaches was monitored using headache diaries at visit 2 and MIDAS-A scores at visit 1, while headache intensity of the patients was assessed using VAS scores at visit 1 and visit 2 along with MIDAS-B scores at visit 1.

MIDAS
MIDAS consists of five questions measuring headache related disability during three activities (school, or paid work; household chores; family, social or leisure activities) covering the past 3 months. The final total score sums up the number of missed days for the abovementioned activities, and categorizes the disability in relation to attack severity as, none or minor disability (scores 0–5), mild disability (scores 6–10), moderate disability (scores 11 to 20) or severe disability (scores ≥21) (12, 15–17). Besides the five listed above, the two other questions were not included in the score, but gave relevant information to the clinician regarding headache frequency (MIDAS A) and pain intensity (MIDAS B) over the past three months (12, 15–17).

HIT-6
HIT-6 items include areas such as vitality, pain, and psychological distress, as well as social, role, and cognitive functioning. Three of 6 items specifically address the previous 4 weeks, while no time period is specified for the remaining 3 questions. Each item is answered using a 5-point Likert scale (6=never, 8=seldom, 10=occasionally 11=very often, 13=always). The final score is determined from the summation of six items, with a range between 36 and 78, with higher scores indicating greater impact, as categorized into four groups including scores ≤49 (little or no impact), scores 50–55 (some impact), scores 56–59 (substantial impact) and scores ≥60 (severe impact) (18, 23) (Figure 2).

Forward and Back Translations of HIT-6
For adaptation of the HIT-6 into Turkish, translation and back-translation methods were used. As for the first step, a native Turkish speaker with fluent English translated the original (English) version into Turkish. And then, a native English speaker translated the Turkish version back into English. The back-translated English version was read and compared with the original HIT-6 in English by two of the authors (PYD, AO), and only then was the Turkish version accepted as the final form of Turkish version of HIT-6 (Figure 3).

Comprehensibility Assessment
Comprehensibility of HIT-6 was assessed using CAF based on self-administered scores in all patients at both visits, and also on physician-

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HEADAHCE IMPACT TEST- HIT-6

To complete, please check one answer for each question.

1. When you have headaches, how often is the pain severe?

| NEVER | RARELY | SOMETIMES | VERY OFTEN | ALWAYS |

2. How often do headaches limit your ability to do usual daily activities including household work, work, school, or social activities?

| NEVER | RARELY | SOMETIMES | VERY OFTEN | ALWAYS |

3. When you have a headache, how often do you wish you could lie down?

| NEVER | RARELY | SOMETIMES | VERY OFTEN | ALWAYS |

4. In the past 4 weeks, how often have you felt too tired to do work or daily activities because of your headaches?

| NEVER | RARELY | SOMETIMES | VERY OFTEN | ALWAYS |

5. In the past 4 weeks, how often have you felt fed up or irritated because of your headaches?

| NEVER | RARELY | SOMETIMES | VERY OFTEN | ALWAYS |

6. In the past 4 weeks, how often did headaches limit your ability to concentrate on work or daily activities?

| NEVER | RARELY | SOMETIMES | VERY OFTEN | ALWAYS |

| COLUMN 1 | COLUMN 2 | COLUMN 3 | COLUMN 4 | COLUMN 5 |
| **(6 points each)** | **(6 points each)** | **(6 points each)** | **(6 points each)** | **(6 points each)** |

To score, add points for answers in each column.

TOTAL SCORE

You should share your results with your doctor. Headaches that stop you from enjoying the important things in life, like family, work, school or social activities could be migraine.

Figure 2. English version of HIT-6

administered scores in subgroup A at visit 1. Each item of HIT-6 was assessed for how well the patient understood the questions as score 1 (well-understood), score 2 (partly understood), score 3 (hardly understood) and score 4 (not understood). The physicians also filled in the form for the patients of subgroup A. During the study period, CAF scores were taken at visit 1 and visit 2, and were then compared to see if there was any change in the patients' comprehensibility level, while the correlation between the visit 1 self-administered and physician-administered scores were also analyzed.

Patient-Physician Reliability
The correlation between self-administered and physician-administered HIT-6 scores at visit 1 was also analyzed in the subgroup A to evaluate the questionnaire's patient-physician reliability.

Reliability Assessment
Reliability (reproducibility and consistency) was assessed with two different methods including test-retest reliability (the connection between visit 1 and visit 2 HIT-6 scores in each patient) and internal consistency (Cronbach's alpha values for visit 1 and visit 2 HIT-6 scores in all patients and for visit 1 self-administered and physician administered HIT-6 scores in subgroup A). The correlation between the internal consistency of visit 1 self-administered and physician-administered scores was also analyzed. The 4-week period between visit 1 and 2 was the predetermined time interval, as it was considered brief enough to rule out any major changes in the disease's severity, and long enough for the patients not to recall their earlier answers from visit 1.

Validity of HIT-6
The validity of HIT-6 was assessed using correlation of HIT-6 scores with headache frequency and intensity parameters including correlations with MIDAS, MIDAS-A, MIDAS-B, headache severity-Likert scale and VAS scores at visit 1 and correlations with headache days for a month (diaries), headache severity-Likert scale and VAS scores at visit 2.

BAŞ AĞRISI ETKİ ÖLÇEĞİ - HIT-6

Tamamlamak için lütfen her soruda bir cevabı daire içine alınız.

1. Baş ağrılarınız olduğunda, ne sıklıkla ağrı şiddetlidir?

ASLA   NADİREN   BAZEN   SIKLIKLA   HER ZAMAN

2. Baş ağrıları ev işi, çalışma, okul veya sosyal aktiviteleri içeren her zamanki günlük aktivitelerinizi yapabilmenizi ne sıklıkta kısıtlar?

ASLA   NADİREN   BAZEN   SIKLIKLA   HER ZAMAN

3. Baş ağrınız olduğunda, ne sıklıkla yatıp uzanmak istersiniz?

ASLA   NADİREN   BAZEN   SIKLIKLA   HER ZAMAN

4. Geçtiğimiz 4 haftada, ne sıklıkla baş ağrılarınız nedeniyle iş veya günlük etkinliklerinizi yapmak için çok yorgun hissettiniz?

ASLA   NADİREN   BAZEN   SIKLIKLA   HER ZAMAN

5. Geçtiğimiz 4 haftada, ne sıklıkla baş ağrılarınız nedeniyle bıkkın veya gergin hissettiniz?

ASLA   NADİREN   BAZEN   SIKLIKLA   HER ZAMAN

6. Geçtiğimiz 4 haftada, ne sıklıkla baş ağrıları iş veya günlük aktivitelere konsantre olabilmenizi kısıtladı?

ASLA   NADİREN   BAZEN   SIKLIKLA   HER ZAMAN

SÜTUN 1	SÜTUN 2	SÜTUN 3	SÜTUN 4	SÜTUN 5
Her biri 6 puan	**Her biri 8 puan**	**Her biri 10 puan**	**Her biri 11 puan**	**Her biri 13 puan**

Toplam puan için her sütundaki yanıtlar eklenir.

TOPLAM PUAN

Eğer HIT-6 skorunuz 50 veya üzerinde ise: Sonuçlarınızı doktorunuzla paylaşmalısınız. Baş ağrıları sizin aile, okul veya sosyal aktiviteler gibi yaşamdaki önemli şeylerden keyif almanıza engel oluyorsa migren olabilir.

Figure 3. Turkish version of HIT-6.

Statistical Analysis

The data were processed and analyzed using STATISTICA 13.3 statistical package. The demographic characteristics of patients were summarized as mean, standard deviations (SD), counts and percentages. Normality assumptions of HIT, MIDAS, MIDAS-A, MIDAS-B, Likert scale and VAS were checked by Shapiro Wilk test. Separate samples t-test and paired t test were used to analyze HIT-6 scores identified by patients vs. physicians and recorded at visit 1 vs. visit 2 among patients, respectively. The Pearson correlation method was used to measure test-retest validity and reliability, and the correlation results were given as Pearson correlation coefficient (R). The internal consistency of HIT-6 scores for the patients and the physicians were assessed using Cronbach's α, and the correlation between internal consistencies of patients' and physicians' HIT-6 scores were studied using the split-half reliability assessment. Cronbach's α, values higher than 0.7 and 0.8 were thought to indicate an acceptable and excellent internal consistency. Statistically, $p < 0.05$ was deemed to be significant.

RESULTS

Clinical Characteristics and Demographics

The study involved 114 patients [mean (SD) age: 35.8 (9.2) years; 60.5% were females] diagnosed with migraine for an average 11.4 years. The majority of participants was classified as episodic migraine (67.5%) and 37.7% of patients were on preventive treatment at study enrollment (Table 1).

Overall Headache Scale Scores

In the overall study population, while no significant change was observed from visit 1 to visit 2 for severity of headache - Likert scale [2.1 (0.6) vs. 1.9 (0.8); p=0.07], VAS scores changed significantly from visit 1 to visit 2 [7.5 (0.7) vs. 6.8 (2.0); p=0.001] (Table 1).

Patients with chronic migraine had significantly higher MIDAS scores at visit 1 [63.7 (42.8) vs. 18.3 (16.4); p<0.001], higher severity of headache-

Table 1. Demographic and clinical characteristics and overall headache scale scores

Patient Demographics		
Gender (female), n (%)		60 (60.5)
Age (year), mean (SD)		35.9 (9.2)
Migraine Characteristics		
Type of migraine, n (%)	Episodic	77 (67.5)
	Chronic	37 (32.5)
Duration of migraine (years), mean (SD)		11.4 (8.8)
Family history for migraine, n (%)		44 (38.6)
Preventive treatment, n (%)		43 (37.7)
Number of NSAID intake per month, mean (SD)	Visit 1	7.5 (9.8)
	Visit 2	5.7 (7.8)
Number of triptan intake per month, mean (SD)	Visit 1	1.2 (2.7)
	Visit 2	1.1 (2.8)
Headache (severity, frequency, intensity) scores, mean (SD)		
MIDAS scores- visit 1, mean (SD)	Total	26.9 (23)
	MIDAS A	28.7 (23)
	MIDAS B	7.1 (1.6)
Likert scale- Severity of headache	Visit 1	2.1 (0.6)
	Visit 2	1.9 (0.8)
	p value	0.07
VAS score	Visit 1	7.5 (0.7)
	Visit 2	6.8 (2.0)
	p value	**0.001***

NSAID: Non-steroidal anti-inflamatory drugs, SD: Standard deviation, VAS: Visual Analogue Scale, MIDAS: Migraine Disability Assessment Scale, MIDAS A: Headache frequency over a three-month course and MIDAS B: Pain intensity (0= no pain; 10= very severe pain) over a three-month course. The severity of headache upon to patient's daily activities was assessed using a 4-point Likert scale as (0) no, (1) mild, (2) moderate and (3) severe, *= p<0.05
Paired t test

Likert scale scores [2.2 (0.8) vs. 1.8 (0.8); p=0.029] in visit 2, and higher VAS scores both in visit 1 [8.0 (1.5) vs. 7.2 (1.6); p=0.007] and visit 2 [7.6 (1.8) vs. 6.4 (2.0); p=0.001] compared to patients with episodic migraine. No significant difference was noted between episodic and chronic migraine patients in terms of visit 1 [64.0 (5.7) vs. 64.4 (7.2); p=0.745] and visit 2 [62.0 (7.1) vs. 64.2 (6.7); p=0.118] HIT-6 scores, while a significant decrease was noted in HIT-6 scores from visit 1 to visit 2 only among patients with episodic migraine (p=0.018).

Comprehensibility
Patients identified that HIT-6 items were "well-understood" at both visit 1 (ranged from 88.6% to 95.7%) and visit 2 (ranged from 93% to 98.2%). Physician-based evaluation at visit 1 also revealed high rates for "well-understood" items by patients (ranged from 96.5 to 98.2%) (Table 2).

There were significant correlations between patient and physician assessments on comprehensibility for all items [R ranged 0.3593 to 0.6593; p ranged 0.006 to <0.001] except for item 4 (Table 2).

Higher rates for "well-understood" was identified by patients in visit 2 than in visit 1 [98.3% vs. 90.4% ; p=0.006] for item 4 and by physicians as compared with patients [96.5% vs. 86.0% ; p=0.024] for item 1 at visit 1 (Table 2).

Patient-Physician Reliability
Visit 1 scores related to self-administered and physician-administered HIT-6 scores showed no statistically significant difference (p=0.0928) but a highly positive correlation (r=0.876, p<0.001) (Table 3).

Internal Consistency
Internal consistency analyzed via Cronbach's α values for visit 1 and visit 2 HIT-6 scores in all patients were 0.753 (acceptable) and 0.864 (excellent), respectively (Table 3).

Table 2. Comprehensibility of HIT-6 items for visit 1 vs. visit 2 application by patients and for visit 1 application by patients vs. physicians

All Patients (n=114)	HIT-6 Items (self-administered scores)											
	Item 1		Item 2		Item 3		Item 4		Item 5		Item 6	
	Visit 1	Visit 2	Visit 1	Visit 2	Visit 1	Visit 2	Visit 1	Visit 2	Visit 1	Visit 2	Visit 1	Visit 2
Comprehensibilit, n(%)												
Well-understood	101(88.6)	106(93.0)	109(95.6)	112(98.2)	109(95.6)	110(96.5)	103(90.4)	112(98.3)	108(94.7)	111(97.4)	108(94.7)	111(97.4)
Partly-understood	7(6.1)	4(3.5)	3(2.6)	2(1.8)	1(0.9)	2(1.7)	5(4.4)	2(1.7)	1.8(1.8)	2(1.7)	2(1.8)	1(0.9)
Hardly-understood	6(5.3)	3(2.6)	2(1.8)	-	4(3.5)	1(0.9)	6(5.3)	-	3.5(3.5)	1(0.9)	4(3.5)	1(0.9)
Not understood	-	1(0.9)	-	-	-	1(0.9)	-	-	-	-	-	1(0.9)
P (Visit 1 &Visit 2)[a]	0.452		0.129		0.713		0.006*		0.340		0.599	

Subgroup A (n=57)	HIT-6 Items (self-administered and physician-administered scores at visit 1)											
	Item 1		Item 2		Item 3		Item 4		Item 5		Item 6	
	Self-reported	Physician-reported	Self-reported	Physician-reported	Self-reported	Physician-reported	Self-reported	Physician-reported	Self-reported	Physician-reported	Self-reported	Physician-reported
Comprehensibilit, n(%)												
Well-understood	49(86.0)	55(96.5)	55(96.5)	56(98.2)	53(93.0)	56(98.2)	52(91.2)	56(98.2)	53(93)	56(98.2)	54(94.7)	56(98.2)
Partly-understood	4(7.0)	2(3.5)	-	1(1.8)	-	1(1.8)	1(1.8)	1(1.8)	2(3.5)	1(1.8)	-	1(1.8)
Hardly-understood	4(7.0)	-	2(3.5)	-	4(7)	-	4(7)	-	2(3.5)	-	3(5.3)	-
Not understood	-	-	-	-	-	-	-	-	-	-	-	-
P (Visit 1 &Visit 2)[b]	0.024		0.317		0.317		0.083		0.180		0.180	
Correlation[c] R	0.3880		0.6593		0.6593		0.1981		0.3593		0.6593	
p	0.003*		<0.001*		<0.001*		0.1395		0.006*		<0.001*	

HIT-6: Headache Impact Test, R: Pearson correlation coefficient, *= p<0.05
[a]Paired t test, [b]Independent samples t-test , [c]Pearson correlation analysis

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Table 3. Test-retest reliability and internal consistency of HIT-6

Self-administered scores		HIT-6 scores Mean (SD)	p value[a] (Visit 1 vs. visit 2)	Test-Retest Reliability Correlation between scores[c]		Reliability (internal consistency) (Cronbach-alpha coefficient)
				R	p	
All patients (n=114)	Visit 1	64.13 (6.20)	0.0765	**0.437**	0.0004	0.753
	Visit 2	62.70 (7.04)				0.864
Subgroup A (n=57)	Visit 1	64.54 (5.30)	0.053	**0.4042**	0.021	0.689
	Visit 2	62.64 (7.94)				0.896
Remaining patients (n=57)	Visit 1	63.71 (7.02)	0.291	**0.5025**	0.005	0.803
	Visit 2	62.74 (6.08)				0.809

Self- vs. physician-administered scores		HIT-6 scores Mean (SD)	p value[b] (Self vs. physician)	Patient-physician reliability Correlation between scores[c]		Reliability (internal consistency) (Cronbach-alpha coefficient)
				R	p	
Subgroup A (n=57)	Visit 1- self administered	64.54 (5.30)	0.928	**0.876**	<0.001	0.689
	Visit 1-physician administered	65.08 (5.48)				0.673

HIT-6: Headache Impact Test, R: Pearson correlation coefficient; SD: Standard deviation, *= p<0.05
[a]Paired t test, [b]Independent samples t-test, [c]Pearson correlation analysis

Test-Re-Test Reliability

Given the noticeable change in VAS scores from visit 1 to visit 2, a subgroup of patients whose number of days with headache changed 3 days or less from visit 1 to visit 2 was chosen to test-retest reliability, and thus the probable negative effect of severity change on the results was eliminated. Mean (SD) HIT-6 scores of aforementioned patients [64.13 (6.20) and 62.70 (7.04), at visits 1 and 2, respectively; p=0.0765] showed a moderate test-re-test reliability (R=0.437, p=0.0004) (Table 3).

Validity of HIT-6

The HIT-6 score was positively correlated with visit 1 and visit 2 headache severity - Likert Scale [R=0.451 and 0.478, respectively; p<0.001 for each] and VAS [R=0.365 and 0.531, respectively; p<0.001] for each scores, and also with visit 2 headache days for a month (R=0.215, p=0.022). No significant correlation was observed between HIT-6 score and visit 1 MIDAS scores (Table 4).

Table 4. Validity of HIT-6

	Correlation of HIT-6 scores	
VISIT 1	r	p
MIDAS	0.150	0.375
MIDAS-A	0.016	0.927
MIDAS-B	0.234	0.163
Headache severity-Likert Scale	0.451	**<0.001**
VAS	0.365	**<0.001**
VISIT 2	r	p
Headache days for a month	0.215	**0.022**
Headache severity-Likert scale	0.478	**<0.001**
VAS	0.531	**<0.001**

HIT-6: Headache Impact Test, MIDAS: Migraine Disability Assessment Scale, MIDAS A: Headache frequency over a three-month course and MIDAS B: Pain intensity (0= no pain; 10= very severe pain) over a three-month course. The severity of headache upon to patient's daily activities was assessed using a 4-point Likert scale as (0) no, (1) mild, (2) moderate, (3) severe.
Pearson correlation analysis; R: Pearson correlation coefficient, *= p<0.005

DISCUSSION

Our conclusions on the validity and reliability of the Turkish translation of HIT-6 with migraine patients in a clinical setting ranged from acceptable to excellent (R=0.753 and 0.864) internal consistency, moderate test-rest reliability (R=0.437) and validity as correlated with headache severity, VAS and headache days for month of the questionnaire in Turkish patients.

In a psychometric analysis of 11 HIT-6 translations across 14 countries, most translations (Hungarian, Canadian English, Greek, Portuguese, German, Spanish, French, UK English, Dutch, and Hebrew) were reported to be comparable to U. S. English and adequately reliable in all languages with the Cronbach α coefficients above the 0.70 criterion (14).

Similarly, our findings indicate that the internal consistency of HIT-6 was acceptable (0.753) at visit 1 and excellent (0.864) at visit 2 in all patients. This seems also in accordance with previous HIT-6 studies which indicated a good internal consistency of HIT-6 with Cronbach's α values ranging from 0.75 to 0.92 (13, 20, 24, 25).

Our findings also revealed high patient-physician reliability (R=0.876) and a moderate test-re-test reliability (R=0.437) of HIT-6. Although test-re-test reliability values for HIT-6 has been reported to range from 0.77 to 0.80 in most studies (13, 20, 24, 25), a moderate level of test-retest reliability (R=0.50) was also reported in patients with migraines or tension type headache (26).

In addition to those stated above, our findings support the sufficiency of the range of HIT-6 scores in determining the level of headache-related disability of the patients who seek headache-specialty care and its potential to measure headache impact (14, 24).

In our cohort, HIT-6 had excellent comprehensibility for at least 90% of patients at both visits, while two items showed a significant difference between visits among patients (item 4) and between patients and physicians in visit 1 (item 1). Specifically, item 4 ("In the past 4 weeks, how often have you felt too tired to do work or daily activities because of your headaches?") was well-understood by higher percentage of patients in visit 2 than in visit 1 (98.3% vs. 90.4%, p=0.006), while percentage of

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patients who well-understood item 1 ("When you have headaches, how often is the pain severe?") was considered to be higher by physicians administered than by patients themselves (subgroup A) [96.5% vs. 86.0%; p=0.024] in visit 1. In addition, there were significant correlations between patient and physician assessments on comprehensibility for all items [R ranged from 0.3593 to 0.6593, p ranged from 0.006 to <0.001] except for item 4. This seems notable given the consideration of item 4 of HIT-6 to measure the least headache impact with lesser likelihood of discerning differences in headache severity clinically (14).

The VAS scores of our patients were significantly changed from visit 1 to visit 2, so a subgroup of patients whose number of days with headache changed 3 days or less from visit 1 to visit 2 was chosen to test-retest reliability to eliminate the potential impact of change in severity on the results. The mean (SD) HIT-6 scores of this subgroup of patients were similarly high in visit 1 and visit 2 [64.54 (5.30) vs. 62.64 (7.94); p=0.053] with a good correlation of scores between visits (R=0.4042, p=0.021). This seems to indicate on the basis of HIT-6 scores that all participants suffered from severe disability due to migraine in both visits. In our study, severe disability due to headache was evident for both visits not only in chronic migraine patients but also in episodic migraine patients. Accordingly, our findings support the past study on psychometric properties of HIT-6 translated to several languages which indicated that scale means of HIT-6 were similar across languages, being 64.30 on average and above 60 for all languages, highlighting a likelihood of headaches to have a very severe impact on participants in all countries (14).

HIT-6 was reported to be correlated significantly with total MIDAS (R=0.56), headache pain severity (R=0.46) and number of headache days per month (R=0.26), while also considered to be a valid instrument to make distinction for headache impact between episodic and chronic migraine (20).

In our cohort, HIT-6 score was positively correlated with headache severity - Likert scale (R=0.451 and 0.478, respectively) and VAS (R=0.365 and 0.531, respectively) scores at visit 1 and visit 2, and also with visit 2 headache days for a month (R=0.215), whereas no significant correlation was noted between HIT-6 score and visit 1 MIDAS scores. Nonetheless, it should be noted that while both MIDAS questionnaire and the HIT-6 are PRO tools, the aspects of headache-related disability [objective/lost time due to headache in MIDAS whereas, subjective/impact of headaches on patients' life in HIT-6] and constructs assessed by the two instruments is considered to differ as is the used recall period (3 months vs. 1-month, respectively) (20).

In addition, our findings indicate that HIT-6 cannot differentiate between chronic migraine and episodic migraine in Turkish population, while other scales used to evaluate headache intensity and frequency (MIDAS, Likert scale or VAS) were able to discriminate for episodic vs. chronic type of migraine for at least one visit.

Nonetheless, while no significant difference was noted between chronic and episodic migraine patients in terms of HIT-6 scores at both visits, a significant change from baseline HIT-6 scores was noted only among episodic migraine patients. Similarly, Persian HIT-6 was also reported to be a valid and reliable questionnaire for the evaluation of headache, whereas authors noted that it cannot differentiate between chronic migraine, episodic migraine, and tension-type headache in Iranian population (26).

Certain limitations to this study should be taken into consideration. First, we relied on the patients' memory for the headache frequency, which was determined based on items A of MIDAS, which requires remembering headache frequency over a 3-month time period. Hence, while 77 (67.5%) and 37 (32.5%) patients were classified into episodic and chronic migraine categories at visit 1, re-classification of patients based on completed headache diaries for a past month at visit 2 revealed 92

(80.7%) and 22 (19.3%) patients to be classified as episodic and chronic migraine, respectively. This finding emphasizes the fluctuating nature of migraine frequency, and thus underlines the importance of headache diaries for accurate diagnosis of migraine types, as well as for selection of therapy and monitoring of therapeutic response. Second, participation of lower number of chronic vs. episodic migraine patients in this study might have affected the results of correlation analysis between MIDAS and HIT-6 scores, as well as the potential of HIT-6 to differentiate migraine types. Third, given the significant change in VAS scores from visit 1 to visit 2, test-retest reliability was carried out in a subgroup of patients with up to 3 days change in the frequency of headache days from baseline visit to eliminate the possible detrimental effects of fluctuating frequency and level of severity of migraine attacks on the study findings.

To sum up, in terms of internal consistency, these results indicates that the Turkish translation is equivalent to the English version of HIT-6, while there is moderate test-retest reliability and validity as correlated with headache severity - Likert scale, VAS and headache days for a month. The Turkish translation of HIT-6 proved to be just as valid when used by physicians in determining the impact of headaches as a patient-reported outcome tool self-administered by both episodic and chronic migraine patients. However, HIT-6 seems not to be able to discriminate for episodic vs. chronic type of migraine in Turkish patients with migraine, which seems to be possible for MIDAS, Likert scale-headache severity or VAS instruments for at least at one session.

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