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Original Article

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Transculturally Adaptation and Validation of the Basel Assessment of Adherence to Immunosuppressive Medication Scale (BAASIS©) Interview Questionnaire Among Turkish Kidney Transplant Recipients

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The study results were presented as a poster at the 19th Congress of the European Society for Organ Transplantation in 2019.

ABSTRACT

Objective: Kidney transplantation provides better survival and quality of life. Non-adherence to immunosuppressive treatment is a prognostic indicator for poor long-term post-transplantation outcomes. Questionnaires are one of the instruments for adherence evaluation. We aimed to transculturally adapt and validate the Basel Assessment of Adherence to Immunosuppressive Medication Scale Interview Questionnaire among Turkish kidney recipients.

Methods: The Basel Assessment of Adherence to Immunosuppressive Medication Scale Interview Questionnaire was applied to 125 recipients. The questionnaire consisted of 5 questions (Q) and a 10 cm Visual analogue scale assessing overall medication adherence over the last 4 weeks except Q4. Q4 assessed adherence over the last year. Guillemin protocol was used for translation and transcultural adaptation. Psychometric tests were performed for reliability (kappa coefficient and Cronbach's alpha) and validation (content and construct validities).

Results: A total of 125 adult kidney recipients, followed for at least 1 year after transplantation were included. The mean following time was 63.9 ± 44.8 months. The mean serum creatinine level was 1.45 ± 0.77 mg/dL and the eGFR value was 60.3 ± 24.4 mL/min/1.73 m^2. The participants were on tacrolimus- (60.5%), cyclosporine- (26.6%), and everolimus-based (12.9%) immunosuppressive regimen. There was no disagreement about the processes including translation in Turkish, and re-translation to English between the researchers. The transculturally adapted questionnaire has a kappa coefficient of 0.915 which indicates excellent reliability, and a Cronbach's alpha coefficient of 0.454 which indicates acceptable internal consistency. For construct validity, factorial loads were 0.756, 0.779, 0.829, 0.393, and 0.032 for questions 1a, 1b, 2, 3, and 4, respectively.

Conclusion: We conclude that the validated Turkish version of the BAASIS© Interview Questionnaire with satisfactory psychometric tests can contribute a practical approach to determine immunosuppressive treatment adherence in Turkish kidney recipients.

Keywords: Kidney transplantation, recipient, treatment, immunosuppression, adherence

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INTRODUCTION

Kidney transplantation success is closely connected to immunosuppressive treatment (IST) management. Tailoring the IST is crucial that should be adequate to prevent rejection and not be excessive to avoid its deleterious effects. Primarily, the medical team is responsible for this management and appropriate prescriptions should be arranged properly for each recipient meticulously during the post-transplant period. Furthermore, adherence to prescriptions is essential for IST efficacy and a disregarding issue in practice.

Immunosuppressive treatment adherence (ISTA) is closely associated with short- and long-term graft

function, quality of life, and increased healthcare costs.[1-4] Besides aforementioned detrimental consequences, ISTA could be improved by education, reorganizing the prescription and resolving the causatives.[5] To improve ISTA, an assessment of adherence should be held initially. Several instruments are available for evaluating adherence; however, there is no reported gold standard instrument in practice.[6] Questionnaires are one of the measurement instruments for adherence which are practical to use. In the literature, The Basel Assessment of Adherence to Immunosuppressive Medication Scale (BAASIS©) is favored as one of the most optimal scales.[7,8] We aimed to transculturally adapt and validate the BAASIS© Interview Questionnaire to investigate ISTA among Turkish kidney recipients.

METHODS

In this single-center cross-sectional study, we initially have received written permission to validate the English version of the BAASIS© Interview Questionnaire in Turkish from Sabina M. De Geest. Ethical approval (Date: 10.06.2016, Decision No: 2016-11/8) was obtained from the institutional review board of Bursa Uludag University University and all participants provided written informed consent.

Study Population

The study was conducted at the Bursa Uludağ University School of Medicine, Nephrology Department, between July 2016 and December 2016. Kidney transplantation has been performed since 1988 and a total number of 1109 recipients have been transplanted at our center. The average annual number of transplantation is 50, and the total number of patients currently followed up is approximately 800. Kidney transplantation recipients who were 18 years old of age or older, with transplantation duration of at least 1 year, and signed informed consent were included in the study. Transcultural adaptation, reproducibility, and reliability tests were assessed in a subgroup of 25 kidney recipients. Validation was studied in 125 recipients with the final version.

MAIN POINTS

- Adherence to immunosuppressive treatment is underestimated which is very important for long-term graft outcome. Immunosuppressive treatment adherence could be improved by education, reorganizing the prescription and resolving the causatives. To improve ISTA, an assessment of adherence should be held initially.
- Although there is no reported gold standard instrument in practice, questionnaires are one of the assessment instruments for adherence which are practical to use. Practical questionnaires like Basel Assessment of Adherence to Immunosuppressive Medication *Interview Questionnaire* can be used for assessing adherence.
- The validated Basel Assessment of Adherence to Immunosuppressive Medication *Interview Questionnaire* can be applied to Turkish kidney transplant recipients during routine outpatient visits and help to improve graft outcomes.

The BAASIS© Interview Questionnaire

The BAASIS© was developed by the Leuven-Basel Adherence Research Group to assess ISTA in adult and adolescent transplant recipients. There are 2 versions of the BAASIS©, the BAASIS© *Interview Questionnaire* and the BAASIS© *Written Questionnaire*, which is applied to the recipient by a healthcare professional as an interview and is completed by transplant recipients on their own, respectively. The BAASIS© *Interview Questionnaire* is the recommended form by the Leuven-Basel Adherence Research Group. The original version of the questionnaire was obtained from Sabina De Geest by e-mail.

The BAASIS© *Interview Questionnaire* begins with a table that should be completed by the healthcare professional and the patient together, documenting which immunosuppressive medications the patient is currently taking, how many tablets of each medication, and at what times. It consists of 5 questions (Q) (Q1a, Q1b, Q2, Q3, and Q4) and a 10 cm visual analogue scale (VAS) assessing overall medication adherence over the last 4 weeks except Q4. Q4 assesses the adherence over the last 1 year. The questionnaire evaluates all the recently defined components of adherence that are initiation, implementation, and persistence[8] as well as overall adherence. Q1a, Q1b, Q2, and Q3 are evaluating implementation, assessing taking medication and drug holidays, timing or regularity of medication intake, and dose reduction Q4 is evaluating persistence. All items start with a YES/NO question. If the answer is YES for Q1a, Q1b, and Q2, then these are followed by 5 response categories that specify the severity of implementation problems. Q1b is only completed if the answer to Q1a is YES. Any YES answer to one of the Q1a, Q1b, Q2, or Q3 indicates an issue with implementation. “YES” answer to Q4 indicates non-persistence of immunosuppressive treatment.

Overall adherence is assessed by answers to Q1a, Q1b, Q2, Q3, and Q4 or using VAS. A recipient answering “NO” on all Qs (Q1a, Q1b, Q2, Q3, and Q4) is considered to be adherent overall. Any YES answer to one of the Q1a, Q1b, Q2, Q3, or Q4 indicates non-adherence.

Study Design

The BAASIS© Interview Questionnaire was applied to participants by the corresponding author at their regular outpatient visits. Guillemin protocol which consists of translation by different researchers, synthesis, back translation, reviewing, and pre-testing steps was applied for translation and transcultural adaptation.[9] Psychometric tests were performed for reliability (kappa coefficient and the Cronbach’s alpha) and validation (content and construct validities).

Translation and Transcultural Adaptation

The process of transcultural adaptation includes translation, back translation, researchers’ committee evaluation, and pretesting. The English version of the *BAASIS© Interview Questionnaire* was translated into Turkish by 3 different

researchers. The elementary translated versions were synthesized and compared, and the first Turkish version that was agreed on was obtained. Next, it was back-translated into English by an independent translator, and the new version in English was compared with the original version in terms of meaning and comprehensibility. Subsequently, the second Turkish version of the *BAASIS© Interview Questionnaire* was approved. The second Turkish version was revised by the research members and the third version was configured.

Psychometric Properties

Reliability Evaluation

The third version was applied to 25 recipients, and after 1 week the instrument was repeated by the same researcher. All the 25 participants involved in test–re test had no doubts in meaning or understanding. The final version of the scale was obtained after the test–retest reliability evaluation, which was evaluated by calculating the kappa coefficient.

Internal Consistency

The final version was applied to 125 participants, of whom 25 were participants re-tested. The internal consistency of the instrument was evaluated by Cronbach's alpha coefficient in 125 participants.

Validation

1. *Content validity* was established by different researchers during the translation and transcultural adaptation process.
2. *Construct validity* was evaluated by exploratory factorial analysis using principal components estimates for factor loadings and the Kaiser–Guttman criterion for dimensionality assessment (eigenvalue ≥1).

Statistical Analysis

Descriptive statistics were expressed as the mean ± SD and ratios, respectively. All analyses were performed using the The Statistical Package for Social Sciences version 22.0 software (IBM Corp.; Armonk, NY, USA)

RESULTS

Study Population

A total 125 (45.1 ± 11.3 years old, 42% deceased donor, 52% female) adult kidney recipients were included in the study. The mean following time was 63.9 ± 44.8 months. The mean serum creatinine level was 1.45 ± 0.77 mg/dL, eGFR value was 60.3 ± 24.4 mL/min/1.73 m^2. The participants were on tacrolimus- (60.5%), cyclosporine- (26.6%), and everolimus-based (12.9%) immunosuppressive regimens (Table 1).

Table 1. The Characteristics of the Participants

	All Participants (N = 125)
Gender (male/female)	60/65
Age (years) (mean ± SD)	45.1 ± 11.3
Donor type (deceased/living)	52/73
Following time (months) (mean ± SD)	63.9 ± 44.8
eGFR (mL/min/1.73 m^2)	60.3 ± 24.4
Serum creatinine (mg/dL)	1.45 ± 0.77
Immunosuppressive protocol	
Tacrolimus based (%)	60.5
Cylosporin based (%)	26.6
Everolimus based (%)	12.9

Translation and Transcultural Adaptation

There was no disagreement about the processes, including translation in Turkish and re-translation to English, between the researchers. The committee agreed on the third version with no doubt.

Reliability

The kappa coefficient was calculated 0.915 by test-retest reliability method which was applied to the subgroup of 25 recipients. The kappa coefficient indicates excellent reliability (>0.9). The Cronbach's alpha coefficient was 0.339 that indicated inadequate internal consistency. When we excluded the Q1b, the Cronbach's alpha coefficient elevated to 0.454.

Content Validity

During the translation and transcultural adaptation process, there were no reported doubts about understanding the questionnaire from the researchers. When we asked the subgroup of 25 recipients during the questionnaire, it was stated that they could understand every question clearly. The final version of the questionnaire was decided according to reliability and content validity results.

Construct Validity

According to principal components analysis and Kaiser–Guttman criterion, the first 2 eigenvalues (1.529 and 1.032) accounted for 64% of the total variance. Factorial loads of the Qs were shown in Table 2. The exploratory factorial analysis demonstrated that Q1a, Q1b, Q2, and Q3 had adequate factorial loads. However, Q4 did not show a good factorial load. When we excluded Q4, the reliability of scale was decreased. In the end, when Q4 was retained and Q1b excluded, adequate factorial loads and Cronbach's alpha coefficient were obtained.

DISCUSSION

Immunosuppressive treatment adherence is an important indicator of graft outcome. Transplant recipients have to take a handful of drugs because of immunosuppressive medications

Table 2. Factorial Analysis of the Adapted Turkish Version

Questions	Factorial Loads (Without *Q*1b)	Factorial Loads (with All *Q*s)
1a	0.478	0.756
1b	—	0.779
2	0.864	0.829
3	0.210	0.396
4	0.193	0.032

and even several other drugs for co-morbidities . Besides that, timing and dosing of immunosuppressive agents are essential for adequate and harmless immunosuppression. It is reported that even slight deviations from prescription are associated with late acute rejection, graft loss, and poor graft outcome.[1-4] As a result because of the aforementioned deleterious consequences, ISTA should be considered as an important issue in recipients.

Adherence is defined by WHO as "the extent to which a person's behavior-taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from health care provider."[10] Non-adherence is defined as a deviation from the prescribed regimen sufficient to influence adversely the regimen's intended effect.[11] Problems with taking, dosing, and timing the prescribed regimen are considered as non-adherence.

There are several methods to measure adherence. The objective methods include direct observation, electronic devices, drug levels, prescription, and refill records. The direct observation of drug swallowing is the only objective-direct method that is impractical to use. The other objective methods are all indirect measurement ways for adherence assessment. Self-report scales, questionnaires, and personal observation are indirect and subjective methods to measure adherence. Among all these, there is no gold standard method for adherence evaluation.[6] Although combining the instruments is considered to be the preferred process to measure the adherence properly,[5,11] it is not practical. Self-report scales are generally applied and frequently used instruments for adherence assessment. There are several scales to determine adherence in the literature. However, ISTA evaluation in transplant recipients has to be customized because adherence assessment should be more meticulous for IST compared with other therapies. Furthermore, the instrument should have sufficient psychometric properties regarding reliability and validity.[7]

Dobbles et al[7] evaluated 14 of the instruments available in European transplant centers for their psychometric properties. *BAASIS©* is recommended as an instrument which questions the possible problems about the prescribed regimen, practical to use, and easy to decide about adherence. The *BAASIS©* has been validated in patients with HIV and kidney transplant recipients, and it is reported that the instrument has good concurrent and predictive validity.[12-14] With this background, we aimed to perform the psychometric tests regarding reliability and validity of the *BAASIS©* questionnaire in Turkish kidney transplant recipients. The *BAASIS©* questionnaire has 2 forms as an interview and a self-report written form. We preferred to adapt the interview form as the Leuven-Basel Adherence Research Group recommended us. The Immunosuppressant Therapy Adherence Scale® (ITAS®) was previously validated in the Turkish transplant population.[15] The scale was developed by Morisky et al in 1986 to evaluate the compliance of patients with hypertension to antihypertensive drugs and was adapted to organ transplant patients by Chisholm et al in 2004. Compared with *BAASIS©*, ITAS® evaluates the ISTA within the last 3 months and developed in a hypertensive population.[16] Whereas, *BAASIS©* questionnaire evaluates all the recently defined components of adherence that are initiation, implementation, and persistence[8] as well as overall adherence. Additionally, the *BAASIS©* questionnaire is more practical to evaluate the overall adherence and development in transplant population.

The process of transcultural adaptation includes translation, back translation, researchers' committee evaluation, and retesting. All steps of the process were uneventful. All the 25 participants involved in test-retest had no doubts in meaning or understanding. So the final Turkish version of the *BAASIS© Interview Questionnaire* was obtained.

We performed factorial analysis to assess the construct validity of the transculturally adapted BAASIS©. Because high factorial loads were obtained in only 1 factor, we assumed to be the instrument was unidimensionality. The psychometric tests regarding validity and reliability had also satisfying results with a kappa coefficient of 0.915 which indicated excellent reliability. Regarding the reliability analysis, when we excluded Q1b which decreased the reliability of the transculturally adapted scale, the Cronbach's alpha coefficient was calculated as 0.454 without Q1b and the result indicated acceptable internal consistency. In the original *BAASIS© Interview Questionnaire*, Q1b should be answered only if the answer to Q1a was YES. With this regard, we considered that the effect of Q1b was not prominent so we decided not to exclude the Q1b from the Turkish version of the *BAASIS© Interview Questionnaire.*

Regarding construct validity, Q3 (0.396) and Q4 (0.032) have lower factorial loads. The factorial load of Q4 was close to 0. The Q4 is evaluating persistence which is questioning if the patient has stopped IST within the last year, without the doctor telling. Almost all participants answered Q4 with the same answer as "No." With this regard, this answer and behavior can be expected. We thought that the low factorial load of Q4 might be a consequence of answer similarity of Q4 among individuals. The answer for Q4 was almost same for the entire group. Despite Q4 having the lowest load, we decided to retain Q4 as in

the original version. Otherwise, the scale's reliability decreased. Compatible with Marsicano et al, Q3 has a low factorial load in our findings which was equivalent to Q4 in Marsicano's.[14] Validation process involved content validity and construct validity, whereas content validity results were adequate with no doubts of understanding.

The primary limitation of our study is the low Cronbach's alpha coefficient of 0.454. When we checked inter-item correlations matrix, the range of correlations was (0.547-0.753). Cronbach's alpha is used to assess the reliability or internal consistency of questionnaires. Although a Cronbach's alpha coefficient above 0.7 is preferred, in some cases low levels of alpha may still be quite useful.[17] Several factors can affect the coefficient result such as the number of items in the questionnaire, the number of participants, and the type of items/answers. A low coefficient may mean that there are not enough questions on the test. Additionally, the homogeneity of the study group also affects the coefficient value.[18] If the test is applied to a homogeneous group, the variability in total test scores will decrease and the coefficient will be lower. In our study, the internal consistency of the instrument was evaluated with 125 participants which is more than recommended (n > 50). So the number of participants was adequate for the evaluation of internal consistency. We considered that a low coefficient could be associated with differences among questions' types and the low number of questions (n = 5) in the BAASIS questionnaire. Furthermore, our study group was almost homogeneous consisting of only kidney transplant recipients. With these aforementioned causes which are all associated with the structure of the original questionnaire, we considered transculturally adapted BAASIS© Interview Questionnaire to be acceptable among Turkish kidney transplant recipients for adherence evaluation with excellent reliability (kappa coefficient 0.915) and acceptable internal consistency (Cronbach's alpha coefficient >0.4).

Until August 2022, the *BAASIS©* was applied to many recipients to evaluate ISTA.[19-22] To our knowledge, in the literature, this was the first study that transculturally adapted and validated BAASIS© Interview Questionnaire among Turkish recipients.

CONCLUSION

The psychometric tests regarding the reliability and validity of the *BAASIS© Interview Questionnaire* in Turkish kidney recipients were satisfactory. We concluded that the validated Turkish version of the *BAASIS© Interview Questionnaire* can contribute a practical approach to determine ISTA in Turkish kidney recipients.

Ethics Committee Approval: This study was approved by Ethics Committee of Bursa Uludağ University (Date: 10.06.2016, Decision No: 2016-11/8).

Informed Consent: Written and signed informed consent was obtained from the participants.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept – A.O., A.E.; Design – A.O., A.E.; Supervision – A.O., A.E.; Resources – A.O., N.Y.; Materials – A.O., N.Y; ; Data Collection and/or Processing – A.O., N.Y., F.E.C.; Analysis and/or Interpretation – A.O., G.O., F.E.C.; Literature Search – A.O.; Writing Manuscript – A.O., F.E.C; Critical Review – A.E.; Other – A.Y, O.Ü., S.A., G.O., S.M.D.D.

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Declaration of Interests: The authors have no conflict of interest to declare.

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