Original article

The application of the necessity-concerns framework in investigating adherence and beliefs about immunosuppressive medication among Chinese liver transplant recipients☆

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ABSTRACT

Objective: This study aimed to explore adherence to and beliefs about immunosuppressive medication using the Necessity-Concerns Framework (NCF) in liver transplant recipients.
Methods: A cross-sectional study performed in recipients who were at least 3 months post liver transplantation. A convenience sample of 243 recipients was recruited. Self-reported medication adherence was measured by the Basel Assessment of Adherence with Immunosuppressive Medication Scale (BAASIS). The NCF was operationalized using the Beliefs about Medication Questionnaire (BMQ) to assess the beliefs about necessity and concerns with taking immunosuppressive medication.
Results: One-hundred-forty-five liver transplant recipients were non-adherent (59.67%). Compared to adherers, non-adherers had lower beliefs regarding the necessity of taking immunosuppressive medication and lower scores on the necessity-concerns different from adherers.
Conclusions: Non-adherence is common in liver transplant recipients. Non-adherers hold beliefs that are different from adherers. Efforts to increase adherence should be made by targeting medication beliefs.

1. Introduction

With advanced transplantation procedures and immunosuppressive therapy, the survival rates of liver transplant recipients (LTRs) have improved worldwide. LTRs face a lifelong intake of immunosuppressive medication (ISM) to prevent rejection of the graft. One study reported that 25–50% of LTRs experienced rejection episodes, which were not only related to whether a therapy regimen was effective but also depended on whether the LTRs were adherent to the medical advice of taking ISM and undergoing regular medical follow up.[1] ISM nonadherence is related to an increased risk for late acute graft rejections, late graft failure, and increased healthcare costs.[2–4] Although strict adherence to ISM therapy is important for maintaining the graft function, LTRs do not always completely adhere to their regimen. Studies have shown that the self-reported ISM nonadherence prevalence ranges from 14% to 73% in LTRs.[5–8] However, the prevalence of ISM non-adherence in Chinese LTRs has not been well studied.

Enhancing adherence to immunosuppressive medications for at-risk recipients may prevent adverse outcomes (graft rejection and loss etc.) and improve long-term outcomes in liver transplantation. Recipients' beliefs about their medications appear to be critical to understanding patient adherence practices. Recipients can have concerns about, for example, the side effects of the medication or they may believe that the medication is not necessary for their health. Studies on patients' beliefs have identified the NCF as a useful method for operationalizing key beliefs that influence adherence.[9,10] The Framework argues that beliefs that medication is less necessary (necessity beliefs) or feelings of greater concerns about taking it (concerns) are related to lower adherence to medication, which have been found in many disease populations

(e.g., thalassemia patients, asthma, diabetes, arthritis, and depression).[11–15] The necessity-concerns difference score has also been found to be associated with adherence.[15] Given the importance of adherence to IMS in LTRs, this 'NCF' potentially helps clinicians to understand patients' attitudes and decisions about the ISM regimen and then to better assist their patients. Beliefs about medicines are different among different cultures; therefore, the purpose of this study was to evaluate the adherence to ISM and beliefs about ISM among Chinese liver transplant recipients and compare the beliefs about ISM between adherent and nonadherent recipients.

2. Methods

2.1. Study design and participants

A cross-sectional design was administered in this study and was performed at the outpatient transplant clinic of a general hospital in Beijing. The inclusion criteria for the recipients were as follows: (1) 18 years or older; (2) able to read and understand Chinese; (3) have a functioning liver-only transplant; (4) at least 3 months post-transplant; and (5) voluntary participation. Recipients who had received more than one liver transplant or a simultaneous solid organ transplant were not included.

2.2. Ethics statement

This study was approved by the ethics committee of the Beijing University of Chinese Medicine in Beijing, China. The purpose, risks and benefits of this study were explained to the participants before they were asked to participate. The participants were assured that participation was voluntary, and that choosing not to participate would not influence their clinical care. All the data from the study were assured for confidentiality. Written informed consent was obtained when collecting the data.

2.3. Data collection and measurements

Recipients who had an appointment at the clinic between April 2015 and November 2015 and who met the eligibility criteria were invited to participate in the study. Interested recipients were given the questionnaires and completed them in-person at the time of the clinic visit. A knowledgeable researcher answered any questions that recipients might have about the questionnaires or research program. It took approximately 20–30 min to finish the questionnaires.

ISM adherence was measured by the Basel Assessment of adherence to immunosuppressive medications scale (BAASIS), which (developed by the Leuven-Basel Adherence Research Group) is a self-reported instrument developed to assess the relevant dimensions of ISM adherence,[16] i.e., taking adherence, timing adherence, drug holiday, and dose-reduction in the last four weeks. The BAASIS is a 4-item, 6-Likert scale that has been validated in liver transplant recipients[17] with a Cronbach's alpha of 0.71; when used in other organ transplant recipients,[18] Cronbach's alpha was 0.70. A higher score corresponds to worse adherence. Non-adherence was defined as a BAASIS score of more than 4. The Cronbach's alpha of this scale was 0.69 in the present study.

The beliefs about ISM were assessed using the 10-item Beliefs about Medicines Questionnaire (BMQ), which is a reliable and validated scale.[19] The BMQ includes two subscales that measure the perceived necessity of taking a specific medication for controlling disease (Necessity) and concerns about the potential adverse consequences of taking it (Concern). Reported reliability coefficients for the Necessity and Concern scales ranged from 0.55 to 0.86.[19] All

items are scored on a 5-point Likert scale; the item responses ranged from 1 (strongly disagree) to 5 (strongly agree). The total scores for both the Necessity and Concern scales ranged from 5 to 25. Higher scores indicate a stronger necessity and concern belief. The Cronbach's alpha scores of the two dimensions were 0.87 and 0.85 in the study. Some studies have calculated a "necessity-concern differential" by subtracting the Concern scale score from the Necessity scale score.[15,20] The score was on a differential range from −20 to +20. A positive score indicates that the patients rated their beliefs in the necessity of taking medications higher than concerns about the medication and vice versa. The necessity-concern framework was split at the scale midpoint to create the following 4 attitude groups: ambivalent (high necessity, high concerns); accepting (high necessity, low concerns); indifferent (low necessity, low concerns); and skeptical (low necessity, high concerns).

Demographic and clinical characteristic questionnaires were designed to collect information on the age, gender, marital status, education level, economic burden, health insurance, household registration, employment status, donor type, time post-transplant, and immunosuppressive medications prescribed.

2.4. Data analysis

Statistical analyses were performed using the SPSS 21.0 statistical package (SPSS Inc., Chicago, IL, USA). Prior to data analysis, a test of normality was performed. Categorical variables were described as proportions, and continuous variables that were normally distributed were described as the mean ± SD and median (inter-quartile range: Q1–Q3) for non-normally distributed continuous variables. Student's t test was used to compare the beliefs between the adherence and nonadherence groups (non-adherence was defined as a BAASIS score of more than 4). Two-sided P-values were set at 0.05.

3. Results

3.1. Participant characteristics

A total of 300 questionnaires were distributed, and all were returned; 57 of them were incomplete and considered to be invalid.

Table 1
Socio-demographic and clinical characteristics of participants.

Characteristic	Total sample ($n = 243$)
Age (years, $M \pm SD$)	53.71 ± 9.85, 55 (28–75)
Gender (n/%)	
Male	184 (75.72)
Female	59 (24.28)
Marital status (n/%)	
Married	234 (96.30)
Unmarried/divorced/widowed	9 (3.70)
Employment status (n/%)	
Employed	89 (36.63)
Retired	131 (53.91)
Unemployed	23 (9.46)
Education level (n/%)	
<High school	51 (20.99)
High school/special school	63 (25.92)
College or higher	129 (53.09)
Household registration (n/%)	
Urban	220 (90.53)
Rural	23 (9.47)
Time post-transplant (years) (n/%)	
<=3	90 (37.04)
4–10	128 (52.67)
>10	25 (10.29)